Customer/Distributor Communication

75 North Fairway Drive
Vernon Hills, Illinois 60061
BD.com

FIELD SAFETY NOTICE

URGENT: Medical Device/Drug Notification or Safety Alert or Medical Device/Drug Recall Notification

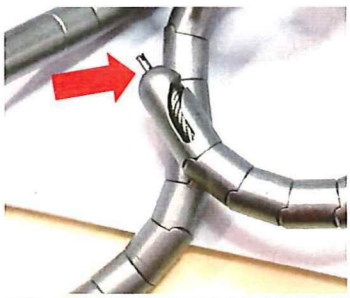
FSCA-RE: RC-VM-2016-0001
DIAMOND-FLEX™ CIRCULAR RETRACTOR, ANGLED, 40MM 5MM
Product Code: 89-6114,
Lot Code(s): 878971; 879366; 879404
Date Code: C16

June-DD-2016

Dear Business Partner:

Product Name:

BD, *formerly* CareFusion, has identified a potential risk associated with a weld failure which could result in the wire protruding thru the tip of the instrument when articulated. If this failure were to occur while in use in a procedure it has the potential to damages tissue or organs

Image of Defect (Wire Protrudes thru Tip) with Device in Retracted Position


Problem Statement/Affected Product:

BD is voluntarily performing a Field Safety Corrective Action to correct affected devices subject to this potential risk.

Affected Product – This notification applies to the following:

#89-6114 DIAMOND-FLEX™ CIRCULAR RETRACTOR, ANGLED, 40MM 5MM Product Code 89-6114,
Lot Code(s): 878971; 879366; 879404
Date Code: C16

See graphics below on where to locate the Product Code; Lot Code; Date Code

Image of Catalog Number (89-6114) & Packaging Lot Number Locations

Product Code 89-6114 Only	Product Code 89-6114 Only	Product Code 89-6114 Only
		
Packaging Lot Number 878971	**Packaging Lot Number 879366**	**Packaging Lot Number 879404**

Image of C16 Date Code Location (Remove Sterilization Sleeve to See Laser Etching on Shaft)

POTENTIAL RISK:

If this failure were to occur while in use in a procedure it has the potential to damages tissue or organs

Zero (0) customer complaints have been received to date.

ACTIONS TO BE TAKEN BY BD:

A credit will be applied to your account for the affected product upon receipt of the affected unit(s)

ACTION TO BE TAKEN BY THE CUSTOMER

- Return the affected unit(s) to:
  BD formerly CareFusion
  75 North Fairway Drive,
  Vernon Hills, Illinois, 60061
  Attention Customer Advocacy
- Include a copy of the response card with the returned unit.

- Please ***promptly return*** the enclosed response card to expedite the correction process and acknowledge receipt of this notification.

The United States Food and Drug Administration 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)
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

For questions and support 1-800-323-9088 Prompt 3
Or email: GMB-US-Complaint-Intake@carefusion.com

We appreciate your ***prompt return*** of the enclosed Response Card to expedite the correction process and acknowledge receipt of this Notification.

We recognize the inconvenience this issue may cause your facility and thank you for your support in this important matter.

Sincerely,

[redacted]

Anna Wehrheim, RN
Manager, Customer Advocacy
Medical and Procedural Solutions
847-362-8063
Anna.wehrheim@BD.com

Enclosure(s): Customer Response Card
FAQ'S

URGENT: Medical Device/Drug Notification or Safety Alert or Medical Device/Drug Recall Notification

FIELD SAFETY NOTICE-CUSTOMER RESPONSE FORM
DIAMOND-FLEX™ CIRCULAR RETRACTOR, ANGLED, 40MM 5MM

Acknowledgment and Verification Form

Product Name: **DIAMOND-FLEX™ CIRCULAR RETRACTOR, ANGLED, 40MM 5MM**

Product Reference: **Product Code: 89-6114,**
Lot Code(s): 878971; 879366; 879404
Date Code: C16

FSCA Identifier: **VMRC-2016-0001**

Name of Hospital / Facility	
Hospital / Facility Address	
Name	
Telephone number	
Email address	
Signature	
Date	

☐ I have read and understand the contents of this Field Safety Notice and confirm that our medical equipment inventory has been checked, and we no longer have in service the list of effected ventilators.

☐ I have read and understood the contents of this Field Safety Notice and confirm that our inventory has been checked and we have the following equipment (see following page).

Equipment Inventory Table:

Model Number	Serial Number

Note: If more space is needed for the above table please attach a separate document.

The following person shall be contacted to coordinate the action (please complete if different than above)

Name	
Telephone Number	
Email	

Please return product with a copy of this form to:

BD, *formerly* CareFusion
75 North Fairway Drive,
Vernon Hills, Illinois, 60061
Attention Customer Advocacy

Product Recall Frequently Asked Questions

DIAMOND-FLEX™ CIRCULAR RETRACTOR, ANGLED, 40MM 5MM

BD *formerly* CareFusion is committed to ensuring patient safety and maintaining the highest level of regulatory compliance with the FDA and other Agency's around the globe.

The Q&A below may help answer some of your questions. Should you have any other questions, contact BD Customer Support at 800.323.9088 (8:00 am CST - 5:00 pm CST).

Q&A

Q: **Why is BD *formerly* CareFusion recalling/removing this product from the marketplace?**

A: As part of BD's commitment to patient safety, a voluntary product recall is being initiated due to a potential patient safety risk.

Q: **How are we communicating this product recall/removal to our customers?**

A: BD is providing this recall communication to our distributors and healthcare facilities that purchased and/or received any of the recalled products.

Q: **How do I receive credit for any recalled product(s)/lot(s) in my possession?**

A: If you are a Healthcare Facility that did **NOT purchase product directly** through BD please contact **your distributor** to initiate the credit process, if required.

If you are a Healthcare Facility **OR** Distributor that **purchased product direct** through BD please perform the following actions:

- Complete and return the **Recall Response Form**
- Call our BD Customer Support Department at 800.323.9088 (Option "3" Monday-Friday 8:00 am CST – 5:00 pm CST. Or email: GMB-US-Complaint-Intake@carefusion.com
- Indicate **"DIAMOND-FLEX™ CIRCULAR RETRACTOR, ANGLED, 40MM 5MM "for** credit.
- Have the quantity for the affected product number needed for credit, which should be the same as indicated on **Recall Response Form**

Q: **What if I have clinical questions regarding this recall?**

A: Customers may contact BD *formerly* CareFusion's Clinical Risk Coordinator, Helen Cox, RN via email at helen.cox@carefusion.com for assistance with any clinical questions.

Q: **Has BD *formerly* CareFusion received any adverse event reports associated with any of the recalled products?**

A: No. BD *formerly* CareFusion has received zero (0) complaints and zero (0) associated reports of death or serious injury related to this issue.

Q: **Is there a patient/user safety issue associated with this product recall?**

A: Yes, a patient safety risk involving the potential of a wire protruding thru the tip of the instrument when articulated. If this failure were to occur while in use in a procedure, it has the potential to damages tissue or organs.

Q: **Can customers (i.e. distributors, healthcare facilities, etc.) ignore this recall?**

A: No. It is important that our distributors and healthcare facilities take prompt action and follow their facility's procedures for destruction of affected product and return the **Recall Response Form**. Attention to this recall is mandated by FDA regulations (specifically, 21 CFR Part 7).

Q: **What should customers do if an adverse event occurs following use of any of the recalled products?**

A: In accordance with standard industry practice, customers must report any adverse event, associated with any products, to BD, *formerly* CareFusion Customer Support and/or the FDA's MedWatch Program via any of the following communication methods:

- **BD *formerly* CareFusion**: 800.323.9088 (option #3 (Monday-Friday 8:00 am CST – 5:00 pm CST) Or email: GMB-US-Complaint-Intake@carefusion.com
- **FDA Web**: MedWatch website at www.fda.gov/medwatch/report.htm
- **FDA Fax**: 1-800-FDA-0178
- **FDA Mail**: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787 (refer to http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm272194.htm for the actual document)

Q: **What steps do customers need to take in support of this recall?**

A: BD *formerly* CareFusion requires customers to take the following steps in a prompt manner:

- Step #1: Inspect current inventory on-hand

- Step #2: Complete the **Recall Response Form** by checking all appropriate boxes and providing all accurate information as necessary.

- Step #3: Return affected unit(s) of all recalled products on hand Return the affected unit(s) to:

  BD *formerly* CareFusion
  75 North Fairway Drive,
  Vernon Hills, Illinois, 60061
  Attention Customer Advocacy
- Include a copy of the response card with the returned unit.

- Please ***promptly return*** the enclosed response card to expedite the correction process and acknowledge receipt of this notification.