CareFusion

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URGENT: PRODUCT RECALL
Vascular Loops

July 22, 2015

Dear Valued Customer:

CareFusion is voluntarily recalling specific Vascular Loop products identified below due to notification from the manufacturing facility that the sterile pouch heat seal may potentially come open during transport. CareFusion **has not** received any customer complaints or adverse events to date related to this issue.

Affected Products / Lot Numbers:

Product Name	Product Code	Lot Number	Expiration Date (YYYY-MM-DD)
Vascular Loop	CH111	031715-3418	2019-03-17
Vascular Loop	CH111	050815-3513	2019-05-08
Vascular Loop	CH111	052115-3540	2019-05-21
Vascular Loop	CH112	033015-3435	2019-03-30
Vascular Loop	CH112	052115-3542	2019-05-21
Vascular Loop	CH113	031615-3417	2019-03-16
Vascular Loop	CH113	050815-3514	2019-05-08
Vascular Loop	CH113	052115-3543	2019-05-21
Vascular Loop	CH114	033015-3436	2019-03-30
Vascular Loop	CH114	050815-3515	2019-05-08
Vascular Loop	CH114	060915-3578	2019-06-09
Vascular Loop	CH115	041715-3478	2019-04-17
Vascular Loop	CH116	033015-3437	2019-03-30
Vascular Loop	CH116	050815-3516	2019-05-08
Vascular Loop	CH116	052215-3545	2019-05-21
Vascular Loop	CH118	042015-3482	2019-04-20
Vascular Loop	CH118	052115-3541	2019-05-21

Potential Risk: This problem may affect patients by impacting the sterility of the device. Product which is not sterile could potentially cause injury to a patient during or following a surgical procedure.

Immediate Actions:
Only product codes and lot numbers identified above are subject to this recall. Please complete the steps listed below in an expeditious manner:

- Immediately quarantine all affected products. Affected products are identified by product code and lot number in the table above.
- Immediately complete and return to CareFusion the enclosed **Recall Response Form (Attachment 1)** via fax at **312-949-9491** or via email at **GMB-GLB-VMfieldactions@carefusion.com.**
- When destroying affected product, please follow your facility's disposal protocol/procedure. If your facility policy does not allow destruction, please contact CareFusion Customer Support at (800) 323-9088 (option #5) (Monday-Friday 8:00 am CST - 5:00 pm CST) for return options.
- **If you purchased product direct** through CareFusion and wish to obtain credit for

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destroyed products, please contact CareFusion Customer Support at (800)323.9088 (option #1) Monday-Friday 8:00 am CST - 5:00 pm CST and indicate "***CareFusion Vascular Loop Recall***"

- If you **did not** purchase directly from CareFusion please contact your distributor directly regarding this recall, including credit inquiry.

Distributors:

- Distributors must notify their affected customers ***immediately*** of this recall.
- Distributors must instruct their customers to respond directly to the distributor, not CareFusion, with any questions regarding credit and/or stock destruction.
- If you choose to use this communication to notify your customers of this urgent recall, please have your customers return the Recall Response Form to you. **Do not** have your customers forward the completed form to CareFusion.

The U.S. Food and Drug Administration has been notified of this action by the manufacturer. 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
- Fax: 1-800-FDA-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

CareFusion appreciates your **immediate attention** to this **URGENT RECALL NOTICE**. If you have any clinical questions related to this recall, please contact Anna Wehrheim, RN, Manager of Medical Specialties at 847-362-8063 or via email at anna.wehrheim@carefusion.com

Regards,

Anna Wehrheim, RN

Anna Wehrheim, RN
Manager of Medical Specialties – Customer Advocacy
CareFusion

Enclosures:
Attachment 1: Recall Response Form

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Attachment 1: Recall Response Form

Customer Name:	
I have read and understand the recall instructions provided in the 22 JUL 2015 letter.	☐ Yes ☐ No
If no, please explain:	
Have any adverse events been associated with recalled product?	☐ Yes ☐ No
If yes, please explain:	

Please complete the following table:

Product Name	Product Number	Lot Number	Expiration Date (YYYY-MM-DD)	Quantity Destroyed / Returned
Vascular Loop	CH111	031715-3418	2019-03-17	
Vascular Loop	CH111	050815-3513	2019-05-08	
Vascular Loop	CH111	052115-3540	2019-05-21	
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