URGENT: PRODUCT RECALL NOTICE

Rigid Intracardiac Sucker Fluted Tip; 1/4” (6.4mm) connector 13” (33cm) length

November 19, 2024

Dear Device Customer,

Surge Cardiovascular is conducting a voluntarily recall of the following devices.

Product Number	Product Name	Lot Number
SUC-4300S	Rigid Intracardiac Sucker Fluted Tip; 1/4” (6.4mm) connector 13” (33cm) length	08294-080724

Surge Cardiovascular has decided to issue a voluntary recall of the affected lot for incomplete or partial pouch seals, which may result in a breach in the sterility. Use of a product not maintaining sterility as a result of incomplete or partial pouch seals may result in patient risk of serious infection.

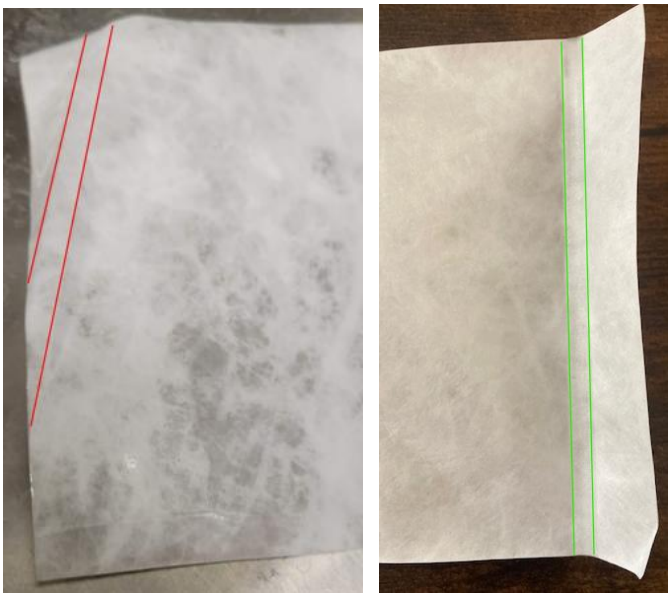

Figure 1: Partial Pouch Seal (left); Good Pouch Seal (right).

Adverse events related to the use of this product should be reported to the FDA’s MedWatch Adverse Event Reporting program either online at www.fda.gov/medwatch/report.htm, by regular mail, or by fax.

MED Alliance Group, Inc. shipping records indicate that your facility has been shipped the affected products.

Actions to Be Taken:

- Immediately discontinue use of the recalled device.
- Segregate and quarantine the product subject to recall.
- Complete Acknowledgement and Receipt Form.
- Dispose of all devices providing Certificate of Destruction, along with disposal pictures.
- Upon completing actions, MED Alliance Group, Inc will send replacement product back to your facility

2140 Oak Industrial Drive NE
Grand Rapids, MI 49505
www.surgecardiovascular.com

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This recall notice should be shared with anyone who needs to be aware within your organization or to any organization where the potentially affected products have been transferred or further distributed to ensure your consignees receive a copy of this recall notice and response form.

The inventory sheet at the end of this letter helps us know what product is still in your possession. We request that you complete this form and return it to us as soon as possible.

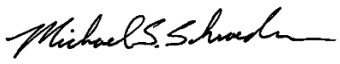
Please contact MED Alliance Group, Inc. (Lindsey Allende) if you need assistance with the the recalled product along with product replacement.

Your support in accounting for the affected devices in your possession is greatly appreciated. If you have any questions about this letter, please contact James Wisniewski jamesw@surgecardiovascular.com or Lindsey Allende lallende@medalliancegroup.com.

Surge Cardiovascular sincerely apologizes for the inconvenience this may have caused you and your patients. The safety of your patients is our top commitment. This recall is being made with the knowledge of the Food and Drug Administration.

If you have any questions regarding this notification, please do not hesitate to contact us at 1-888-891-1200 Ext 102.

Sincerely,



Mike Schroeder
President

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MEDICAL DEVICE RECALL DISPOSAL RESPONSE
Acknowledgement and Receipt Form

Response is Required

I have read and understand the recall instructions provided in the letter, and I have checked my stock and have quarantined inventory consisting of the items listed below.

Product Number	Lot Number	Quantity Disposed (eaches/devices)
SUC-4300S	08294-080724	

Note: Please provide Certificate of Destruction, along with pictures of device disposal.

Any adverse events associated with recalled product? ____Yes / No ____

If yes, please explain:

_____

_____

If you have any questions regarding this notification, please do not hesitate to contact us at 1-888-891-1200 Ext 102 or by email James Wisniewski jamesw@surgecardiovascular.com or Lindsey Allende lallende@medalliancegroup.com.

COMPLETED BY:

Contact Name: _____

Title: _____

Telephone Number: _____

Email: _____

Facility Name: _____

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