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Urgent Field Safety Notice
Perfusion Tubing System Packs

Date: October 05, 2017

Reference: CP-MIR-2017-001

Attention: Surgeons, Hospital Inventory and Risk Management Personnel

Details on affected devices:
The purpose of this letter is to advise you that LivaNova[1] is voluntarily recalling custom Perfusion Tubing System (PTS) packs containing male luer lock connectors that may be partially occluded. This recall is applicable to PTS packs listed in **Attachment 1** of the present communication.

Description of the problem:
Complaints of difficulties draining fluid on lines included in the PTS have been reported. In all cases, partial occlusions of the luer connector were noted by customers. Investigation determined that the reported connector occlusion was generated during molding of one specific lot of luer.

There have been no reported serious injuries regarding this issue; however, the potential for hemolysis, air embolism or myocardial infarction exists if product with this problem is used.

Advise on action to be taken by the user:

1. All PTS with a lot number within range of those in the ***Affected Product List*** in **Attachment 1** should be removed from inventory.

2. Contact your LivaNova sales representative to arrange for the return of the affected product and to order equivalent replacement product.

3. If there is an urgent need to use the PTS to maintain patient care in the medical center, the male luer lock connectors contained in the affected products may be visually inspected following the instructions included in **Attachment 3**.

Transmission of this Field Safety Notice:
Please complete and return the attached Customer Response Form (see **Attachment 2**) by fax to +46 8 50122401 or by email to anders.edvinsson@livanova.com. Please assure that this notice is communicated to all personnel within your organization who need to be aware of it.

If you believe that any adverse reactions have occurred associated with the use of this product, these issues may be reported to LivaNova at anders.edvinsson@livanova.com .

[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries including Sorin Group Italia. In this document, we refer to all entities using the brand name LivaNova.

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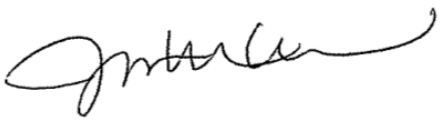
Contact reference person:
For questions regarding this Field Safety Notice, please contact your local representative or e-mail customerqa.sgi@sorin.com.

This action is being conducted with the knowledge of the competent authority of your country and other applicable regulatory agencies.



Joan Ceasar
Director, Customer Quality

Enclosed:
Attachment 1: Affected Product List
Attachment 2: Customer Response Form
Attachment 3: Instructions for Inspections

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Attachment 1: Affected Product List

Affected Product	
Catalog Number	**Lot Number**
Complete this table with specific product details for each customer.	

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Attachment 2: Customer Response Form

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October 2017

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer Information:

Customer Name	
Street Address	
City, State/Province, Country	

I have read and understood the recall instructions provided in this letter. Yes ___ No ___
Have there been any adverse events associated with recalled product? Yes ___ No ___

If yes, please explain and include the best contact person from who we may obtain more information:

_____

_____

_____

_____

Affected Product Information:

Manufacturer's Product Number/Catalog Number	Lot Number	Quantity Returned	Quantity Destroyed	Quantity with Other Disposition *Please use lines above to explain*

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE COMPLETE THE RESPONSE FORM AND RETURN IT VIA FAX TO **+39 (0)535 25229** OR BY E-MAIL TO **customerqa.sgi@sorin.com** no later than **November 30, 2017**.

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INSTRUCTIONS FOR INSPECTIONS

The following instructions may be applied only in absence of alternative product and in case of urgent need to maintain patient care.

Inspection must be performed applying techniques to maintain sterility.

1. Open the connection or remove the protection cap from male luer connectors.
2. Visually inspect male luer connectors for occlusion. Refer to the pictures below to determine conformity of the luer.
3. Restore connection as needed.
4. If a non-conforming luer is identified or in case of doubt, replace the PTS with a new one and contact LivaNova.

NOT CONFORMING

CONFORMING