

Urgent New Field Safety Notice

**Perfusion Tubing System various part numbers
Potential Non-Sterility due to possible deviations of parameters /
processes defined for ethylene oxide sterilization.**

CP-MIR-2021-001

April 8th, 2021

To Attention of: Vigilance responsible, Health care professionals involved stock management

Type of action: Identify, Quarantine and Return devices to manufacturer.

Dear Madam, Dear Sir,

Purpose of this Letter

The purpose of this letter is to advise you that LivaNova ("LivaNova" or "the Company") is executing a field safety corrective action for specific lots of customized Perfusion Tubing System (PTS) circuits.

According to our traceability, you were supplied of one or more devices potentially affected by the issue described below, and, therefore, one or more of these device(s) may be present in your inventory.

Description of the Issue

LivaNova has been informed by its Notified Body and by Italian Competent Authority that one of its sterilization supplier, Steril Milano, was involved in recurrent non conformities in the sterilization process documentation so that its certificate was suspended.

Although initial investigation performed by LivaNova on Steril Milano raw data suggested that LivaNova devices were sterilized in compliance with the validated sterilization process, based on the most recent information received from Steril Milano, LivaNova can not exclude a deviations in the validated processes and has initiated the removal from the field of all the non-expired affected product.

The list of all the affected products distributed to Your facility is provided in Attachment 1 to the present notice. Other LivaNova products not listed in Attachment 1 are not affected by this issue and can be safely used.



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Risk to Health

The risk level associated with the undesirable conditions (sepsis and/or infection) is considered MEDIUM.

As of today, no event of sepsis or infection has been reported to LivaNova relevant to the affected distributed products.

Which Device(s) are Potentially Affected?

Detailed list of potentially affected lots supplied to your facility is provided in Attachment 1 to the present communication. Other PTS lots in your inventory not listed in Attachment 1 are not affected by this issue and can be safely used.

What Actions Should Health Care Professionals Take?

LivaNova is coordinating the removal of all potentially affected PTS lots in your inventory.

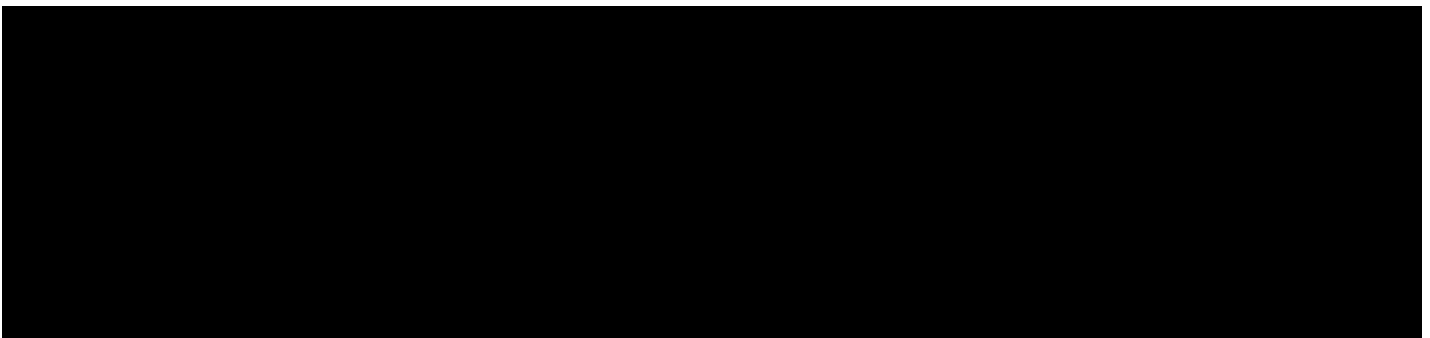
Please ensure timely execution of the following actions:

1. Using the list provided in **Attachment 1**, please check your inventory for potentially affected devices supplied at your facility;
2. All potentially affected devices listed in Attachment 1 and still in inventory **should not be used and should be quarantined**, pending return to LivaNova;
3. Please complete and return the **Attachment 1** by e-mail to LivaNova.FSCA@livanova.com to initiate the removal/replacement process of the devices.

Your LivaNova Representative will contact you to coordinate replacement of the potentially defective device(s)

What Actions Is the Manufacturer Taking?

1. As an immediate action, LivaNova imposed a quality hold on the devices still available in stock and suspended any sterilization service from Steril Milano. All EtO sterilizations are currently executed by LivaNova owned sterilization plant.
2. LivaNova is informing via present notification users of the issue. LivaNova is also advising users to identify, quarantine and return any remaining stock of the potentially affected devices.
3. LivaNova is Coordinating and providing information to the user on product replacement.



Transmission of this Communication

Please ensure that this notice is communicated **to all personnel within your organization who need to be aware and transfer this notice to other organizations on which this action has an impact**. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Your country's Health Competent Authority is informed about this communication to customers, and this action is being reported to other applicable regulatory agencies. Follow-up FSN is not planned for this issue.

Please report all device-related incidents to LivaNova or your local representative, and the national Competent Authority if appropriate, as this provides important feedback.

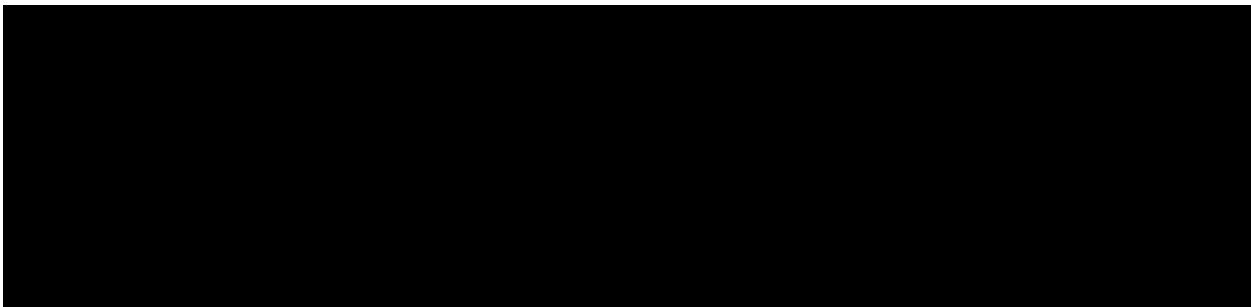
If you have transferred any of the affected devices to a third party, please communicate this information to them and inform the LivaNova Quality Assurance Team at LivaNova.FSCA@livanova.com.

Contact reference person

For questions regarding the information in this letter or regarding the device return and replacement, please contact your usual representative (**Insert local contact details**) or LivaNova Customer Quality via e-mail at LivaNova.FSCA@livanova.com.

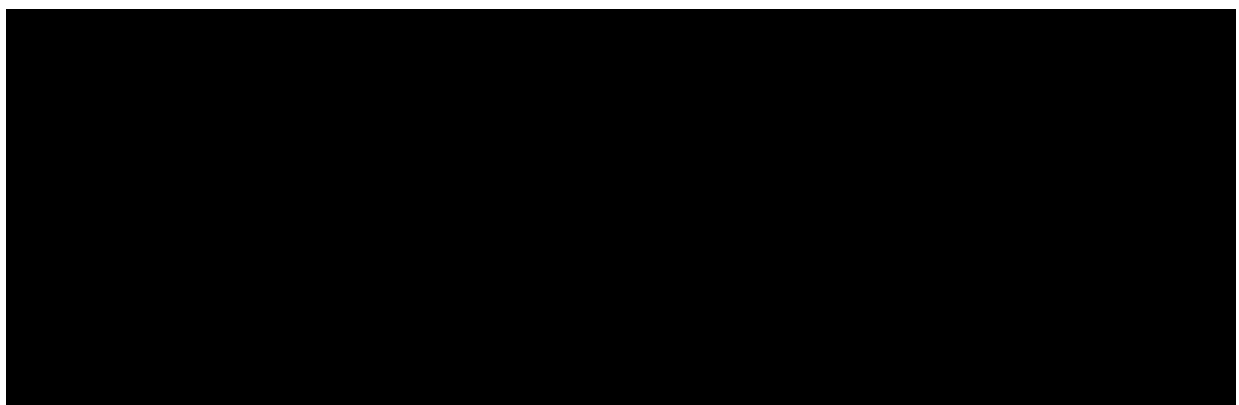
Thank you for your cooperation in this matter. LivaNova is diligently working to resolve this issue. We remain committed to providing quality devices and service to our customers, and we apologize for any inconvenience this situation may have caused.

Sincerely,



Attachment list

Attachment 1: Customer Response Form and Potentially Affected Devices List





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Attachment 1:
Potential Non-Sterility due to possible deviations of parameters /
processes defined for ethylene oxide sterilization
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April 8th, 2021

Customer Information:

Facility/hospital Name

CUSTOMER FACILITY/HOSPITAL NAME

Facility/hospital address

CUSTOMER FACILITY/HOSPITAL ADDRESS

By signing and returning this Customer Response Form, you are acknowledging you have read and understood the notification, and,

We have reviewed and understood the attached notification

☐ Yes ☐ No

This notification has been distributed to all users involved in the use
of potentially affected devices

☐ Yes ☐ No

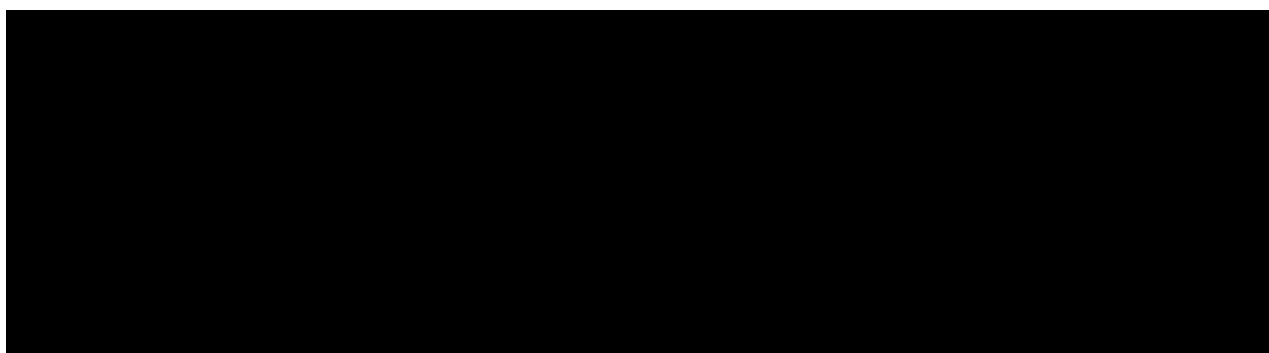
Through the **Affected Product Information Table**, please check your inventory for potentially affected devices and indicate the result of your check:

We confirm all devices still in inventory have been quarantined and
will not be used until they can get returned to LivaNova

☐ Yes ☐ No

Affected Product Information for **FACILITY/HOSPITAL NAME**

Model (item)	Device description	Lot Number	Quantity received	Quantity still in inventory that will be returned	Other important information (if any)
XXXXXX	XXXXXX	XXXXXX	XXXXXX		
XXXXXX	XXXXXX	XXXXXX	XXXXXX		





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To prevent repeat notifications of this notice, please complete all information, sign and return all pages of this Attachment 1 **no later than May 1st, 2021** by e-mail to LivaNova.FSCA@livanova.com.

Name/Title of the person that performed the inventory check	
Signature	
Contact details (e-mail or Phone number)	
Comment / Question (if any)	

LivaNova will contact you to coordinate replacement of the potentially defective device(s).

