LivaNova
Health innovation that matters

Urgent Field Safety Notice
Aortic Cannulae
Catalog numbers RA-1XXX, NA-1XXX

Date: June *xx*, 2017

Reference: CP-ARV-2017-001

Attention: Surgeons, Hospital Inventory and Risk Management Personnel

Details on affected devices:
The purpose of this letter is to advise you that Sorin Group USA, Inc.[1] is voluntarily recalling certain Aortic Cannulae (RA-1XXX, NA-1XXX), indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery.

Description of the problem:
Following an improvement to its inspection process, LivaNova identified that some Aortic Cannulae (RA-1XXX, NA-1XXX) in its inventory contained flash (excess plastic) on the tip of the cannula. This issue may affect product manufactured by California Medical Laboratories and later by Sorin Group USA, Inc.

If flash were to dislodge during use of the product, it may be released into the patient's blood circulation, resulting in the possibility of embolism.

There have been no reported complaints regarding this issue; however, the potential for patient injury exists if product with this problem is used.

Advise on action to be taken by the user:

1. All Aortic Cannulae (RA-1XXX, NA-1XXX) 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.

Transmission of this Field Safety Notice:
Please complete and return the attached Customer Response Form (see **Attachment 2**) by fax to +39 (0)535 25229 or by email to customerqa.sgi@sorin.com. Please assure within your organization that this notice is communicated to all personnel 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 customerqa.sgi@sorin.com.

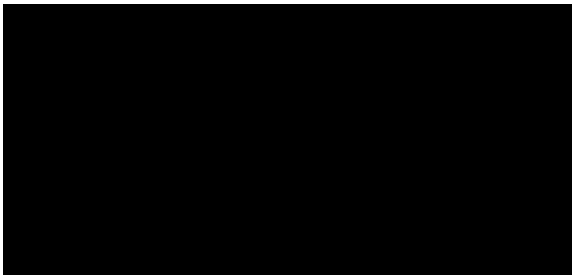
[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including Sorin Group USA, Inc. and California Medical Laboratories, Inc., the manufacturers of the product addressed in this notice. In this document, we refer to all entities using the brand name LivaNova.

LivaNova
Health innovation that matters

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

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

[***Add contact Information for Local representative***]



Enclosed:
Attachment 1: Affected Product List
Attachment 2: Customer Response Form

LivaNova
Health innovation that matters

Attachment 1: Affected Product List

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

LivaNova
Health innovation that matters

Attachment 2: Customer Response Form

Aortic Cannulae, Catalog numbers RA-1XXX, NA-1XXX

June 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

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** no later than **July 30, 2017**.