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.
Contact reference person:
For questions regarding this Field Safety Notice, 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
## Affected Product

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Lot Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Complete this table with specific product details for each customer.*
Aortic Cannulae, Catalog numbers RA-1XXX, NA-1XXX  
June 2017

MEDICAL DEVICE RECALL RETURN RESPONSE  
Acknowledgement and Receipt Form

Response is Required

Customer Information:

<table>
<thead>
<tr>
<th>Customer Name</th>
<th>Street Address</th>
<th>City, State/Province, Country</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Manufacturer’s Product Number/Catalog Number</th>
<th>Lot Number</th>
<th>Quantity Returned</th>
<th>Quantity Destroyed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Signature of Receipt ________________________________________________________________

<table>
<thead>
<tr>
<th>Name/Title</th>
<th>Telephone</th>
<th>Email address</th>
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</table>

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.