

Letter for healthcare professionals

ID: FSCA 02-16

June 15th, 2016

URGENT FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices; Additional Action with Respect to

Avant & Primo2x Families Adult Oxygenator Mounting Brackets

Dear LivaNova Customer,

On June 15, 2015, Sorin Group Deutschland GmbH¹ (SGD) issued a Field Safety Notice (re-issued on August 6, 2015) regarding "Cardiac Surgery Mycobacterium Risks; Disinfection and Cleaning of Sorin Heater Cooler Devices" (attached) to mitigate a potential risk of patient infection by non-tuberculous mycobacteria released from the Heater-cooler 3T.

Sorin Group Italia srl (SGI) is taking an action consistent with the instructions provided in the Step 1 of the Field Safety Notice (FSN) issued by SGD ("*Replace, sterilize and/ or disinfect any accessories and products that are used in conjunction with the heater cooler device ...*") by replacing certain oxygenator mounting brackets that are currently being used with the Heater-Cooler 3T as they could be a source of re-contamination of a clean Heater-Cooler 3T's water circuit.

Specifically, the Oxygenator mounting brackets subject to this action include tubing that connects the Heater-Cooler 3T water circuit to the Oxygenator. This tubing is not subjected to disinfection per the IFU. Therefore, if the Heater-Cooler 3T user failed to clean and disinfect the Heater-Cooler 3T resulting in contamination of the Heater-Cooler 3T and at some point later used Oxygenator mounting bracket, the water from the contaminated Heater-Cooler 3T could cross-contaminate the Oxygenator mounting bracket's internal tubing in which biofilm could develop. If a non-contaminated Heater-Cooler 3T was later connected to an Oxygenator mounting bracket that had been previously cross contaminated, the Oxygenator mounting bracket could contaminate the clean Heater-Cooler 3T.

To mitigate this hazard, SGI is removing these affected Oxygenator mounting bracket models from the marketplace and replacing them with new brackets that have no contact with the Heater-Cooler 3T water circuit. The adult oxygenator mounting brackets that are being replaced are listed in the table below :

¹ Sorin Group Deutschland GmbH and Sorin Group Italia srl are wholly-owned subsidiaries of LivaNova PLC that is a U.K. holding company. In the present document, the brand name LivaNova is also used to refer to either Sorin Group Deutschland GmbH or Sorin Group Italia srl

Affected Oxygenator Mounting Brackets	D632 Adult Open System bracket (catalogue number #05046)
	Adult Oxy module Avant bracket (catalogue number #050128)
	Synthesis "C" bracket (catalogue number #050350)
	Synergy bracket (catalogue number #050131)
	D626 Avant Holder (catalogue number #05040)
	D630 Avant Holder (catalogue number #05041)
	Synthesis Oxygenator Holder (catalogue number #050127)

Our records show that you are in receipt of an affected Oxygenator mounting bracket(s). Therefore, please acknowledge receipt of this letter by completing the attached Customer Response Form and return no later than July 29th, 2016.

Based on the information provided in the Customer Response Form, a LivaNova sales representative will contact you with information on how to disposition the affected Oxygenator bracket and receive a new bracket. The existing brackets can be used until a replacement unit can be provided.

There is no cost to you associated with this service. If you need support for the execution of these actions, please contact your LivaNova sales representative.

Please assure this notice is communicated to all those who need to be aware within your organization. In case you have transferred the affected Oxygenator mounting bracket(s) to a third party, please indicate so on the Customer Response Form.

LivaNova provided the Local Competent Authorities with a copy of this communication to make them aware of this action.

For questions regarding this Field Safety Notice, please contact your LivaNova sales representative, or customerQA.sgi@livanova.com or send a fax at +39 (0)535 25229.

LivaNova is committed to provide quality products and service to its customers and we sincerely apologize for any inconvenience this situation may cause.

Thank you for your cooperation in this matter.

Best regards,


Cristiano Guglielmi
QA Director, Mirandola/Cantù
Cardiac Surgery Business Unit
Sorin Group Italia s.r.l.

Customer Response Form

URGENT FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices; Additional Action with Respect to

Avant & Primo2x Families Adult Oxygenator Mounting Brackets

Customer Name: _____
Address: _____

According to our records, you received one or more of the below affected Oxygenator mounting bracket(s).

Affected Oxygenator Brackets	D632 Adult Open System bracket (catalogue number # 05046)
	Adult Oxy module Avant bracket (catalogue number # 050128)
	Synthesis "C" bracket (catalogue number # 050350)
	Synergy bracket (catalogue number # 050131)
	D626 Avant Holder (catalogue number # 05040)
	D630 Avant Holder (catalogue number # 05041)
Synthesis Oxygenator Holder (catalogue number # 050127)	

I have received, read and understood the cover letter "Disinfection and Cleaning of Sorin Heater Cooler Devices; Additional Action with Respect to Avant & Primo2x Families Adult Oxygenator Mounting Brackets" dated June 15th, 2016.

Yes No

If "no" was indicated in the statement above, please explain:

We have one or more of the above listed affected Oxygenator Mounting Bracket(s) at our location.

Yes No

If "yes" was indicated in the statement above, please specify below how many of each Oxygenator Mounting Bracket(s) **are still in use** at your location.

Affected Oxygenator Mounting Brackets	Qty of brackets presently in use at our location TO BE REPLACED
D632 Adult Open System bracket (catalogue number #05046)	
Adult Oxy module Avant bracket (catalogue number #050128)	
Synthesis "C" bracket (catalogue number #050350)	
Synergy bracket (catalogue number #050131)	
D626 Avant Holder (catalogue number #05040)	
D630 Avant Holder (catalogue number #05041)	
Synthesis Oxygenator Holder (catalogue number #050127)	

Please, specify below how many of each Oxygenator Mounting Bracket(s) **are present but not anymore in use** at your location. These mounting brackets shall be returned to LivaNova or scrapped locally.

Affected Oxygenator Mounting Brackets	Qty of brackets NOT IN USE to be returned or scrapped
D632 Adult Open System bracket (catalogue number #05046)	
Adult Oxy module Avant bracket (catalogue number #050128)	
Synthesis "C" bracket (catalogue number #050350)	
Synergy bracket (catalogue number #050131)	
D626 Avant Holder (catalogue number #05040)	
D630 Avant Holder (catalogue number #05041)	
Synthesis Oxygenator Holder (catalogue number #050127)	

TABLE 1

I declare that units not in use at my location as reported in table 1:

- have been destroyed/discarded in accordance with the local procedure
- will be returned to LivaNova

Please indicate your name and job title, date and sign here below

Name

Title

Signature

Date

Thank you for your cooperation in completing this Customer Response Form.
Please return your LivaNova sales representative **no later than July 29th, 2016.**