

«Name1»
«Name2»
«Name3»
«Address»
«Address»

FIELD SAFETY NOTICE

Use of Sorin Group Deutschland GmbH heater coolers in combination with certain oxygenators with polymer heat exchanger designs

- Affected Devices:** Sorin Group Deutschland GmbH perfusion system – Heater Cooler 1T, Heater Cooler 3T and FlexTherm devices (refer to Attachment 1 for affected catalog and serial numbers)
- Date:** 21. June 2016
- Reference No:** 9611109-06/21/16-004-C
- Attention:** Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionists and other users of these devices
- Reason:** The Instructions for Use of the Heater Cooler 1T, Heater Cooler 3T and FlexTherm devices (“1T/3T/FlexTherm Systems”) prescribe the addition of 50ml and 150ml respectively of medical grade 3% hydrogen peroxide to the filtered tap water in the device, which results in a maximum concentration of 330ppm. The purpose of adding the hydrogen peroxide is to prevent microbial growth between the regular cleaning / disinfection cycles performed every 2 weeks.

LivaNova¹ has determined that certain oxygenators containing a heat-exchanger with a polymer membrane separating the blood compartment from the water compartment, when used with the cleaning and disinfection regimen described in the Instructions for Use versions applicable since 2013, may result in diffusion of a small quantity of hydrogen peroxide from the water side to the blood side during a typical procedure.

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

LivaNova's toxicological assessment has concluded that the Allowable Limit (AL) for hydrogen peroxide transferred to the blood during a typical bypass procedure not exceeding 6 hours is 0.21 mg/day per kg of patient body weight. Practically, this means a limit of (1) 12.60 mg/day for a 60kg adult and (2) 0.63 mg/day for a neonate of 3kg. If the device is used for over 6 hours, a lower limit of 0.034 mg/day per kg of patient body weight applies. Practically, this lower limit means a limit of (1) 2.02 mg/day for a 60kg adult and (2) 0.10 mg/day for a neonate of 3kg.

LivaNova has become aware that certain oxygenators manufactured by third parties may allow diffusion of hydrogen peroxide in a quantity that exceeds the ALs defined by the company.

LivaNova is providing this notification to: (1) inform customers that some oxygenators available on the market may not be compatible with hydrogen peroxide; and (2) provide specifications regarding the compatibility of oxygenators introducing a maximum Allowable Limit for hydrogen peroxide diffusion.

Dear Valued Customer:

The purpose of this letter is to advise you that Sorin Group Deutschland GmbH (“LivaNova” or “the Company”) is executing a voluntary field safety correction for the 1T Heater Cooler, 3T Heater Cooler and the FlexTherm Systems (“1T/3T/FlexTherm Systems”). This field safety notice describes immediate action to be taken by you.

Description of Issue

The Instructions for Use for the 1T/3T/FlexTherm System prescribe the addition of 50ml and 150ml respectively of medical grade 3% hydrogen peroxide to the filtered tap water in the device, which results in a maximum concentration of approximately 330ppm. The purpose of adding the hydrogen peroxide is to prevent microbial growth between the regular cleaning / disinfection cycles performed every 2 weeks.

The Company has determined that plastic heat-exchanger fibers separating the blood compartment from the water compartment in certain oxygenators may allow for diffusion of some quantity of hydrogen peroxide during a typical procedure. LivaNova’s toxicological assessment has concluded that the Allowable Limit (AL) for hydrogen peroxide transferred to the blood during a typical bypass procedure not exceeding 6 hours is 0.21 mg/day per kg of patient body weight. Practically this means a limit of (1) 12.60 mg/day for a 60kg adult and (2) 0.63 mg/day for a neonate of 3kg. If the device is used for over 6 hours, a lower limit of 0.034 mg/day per kg of patient body weight applies. Practically, this lower limit means a limit of (1) 2.02 mg/day for a 60kg adult and (2) 0.10 mg/day for a neonate of 3kg.

LivaNova has become aware that certain oxygenators manufactured by third parties may allow diffusion of hydrogen peroxide in a quantity that exceeds the ALs defined by the Company.

Actions to be taken by the user of the 1T/3T/FlexTherm System

- ✓ If the 1T/3T/FlexTherm System is used with LivaNova oxygenators, no further action needs to be taken, as testing demonstrated that all LivaNova oxygenators are compatible with the determined AL. Continue to follow the current Instructions for Use for cleaning and disinfection of the System.
- ✓ If the 1T/3T/FlexTherm System is used with oxygenator brands other than the LivaNova oxygenators, please strictly adhere to the following new Instructions:
 - Contact the manufacturer of the disposable oxygenators for information specific to permeability rates of the heat exchanger for hydrogen peroxide for a maximum concentration of approximately 330ppm (the maximum concentration that can be achieved by following chapter 5.2 (Filling the Water Tanks) and chapter 6.4 (Changing the Water) of the Instructions for Use.

- Do not use the heater-cooler with disposable oxygenators that have a permeability rate that exceeds the daily allowable limit (AL) of 0.21 mg / day per kg of patient body weight. This means a limit of 12.60 mg/day for hydrogen peroxide for a 60kg adult patient or 0.63 mg/day for neonate of 3 kg for whom the heater-cooler is in use for durations of up to 6 hours. If the device is used for over 6 hours, a lower limit of 0.034 mg/day per kg of patient body weight applies. Practically, this lower limit means a limit of (1) 2.02 mg/day for a 60kg adult and (2) 0.10 mg/day for a neonate of 3kg.
 - Certain patient conditions may pose greater susceptibility to hydrogen peroxide, including but not limited to Vitamin E deficiency, certain heritable deficiencies of enzymes responsible for metabolism of hydrogen peroxide and related compounds, and certain hemolytic anemias. Our toxicological assessment has demonstrated that use of the 3T System devices for durations of six hours or less remains within Allowable Limits for patients with greater susceptibility to hydrogen peroxide.
 - Although Allowable Limits for hydrogen peroxide diffusion are provided, actual performance may vary in individual cases and patient monitoring and management of all patients should be performed in keeping with best practices.
- ✓ If your 1T/3T/FlexTherm System is used with a non-compatible Oxygenator, please perform the following steps **until** the oxygenator is replaced with a compatible product that does not exceed the described permeability rate:
- Stop adding hydrogen peroxide to the tank of the 1T/3T/FlexTherm System.
 - Change the water in the tank on a daily basis instead of every seven (7) days as described the Instructions for Use. Customers should continue to disinfect their machines every two weeks as described in the Instructions for Use.
 - Implement a microbiological monitoring of the water quality by heterotrophic plate count (HPC) measurement.
 - Note: The water in the device should meet microbiological drinking-water quality according to national drinking-water standards (e.g. EPA drinking water standard: <500 cfu/ml).
 - If you find microbial counts in the water are greater than the limits, contact your infection control manager to determine appropriate actions and immediately contact your service representative for support.
 - After the oxygenator is replaced with a compatible product, return to conducting cleaning, disinfection, and water changes as provided for in the Instructions for Use.

Please complete and return the attached Confirmation Form (see **Attachment 2**) by fax to «[Number](#)» or by email to «[E-mail Address](#)».

Transmission of this Field Safety Notice

Please assure within your organization that this notice is communicated to all personnel who need to be aware of this Field Safety Notice. If you have transferred relevant heater cooler(s) to a third party, please communicate this information to them and inform Christian Peis (contact information below).

Please maintain awareness on this notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action.

Contact reference person

For questions regarding this Field Safety Notice, please contact Christian Peis, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agencies, who are aware of these actions.

Thank you for your cooperation in this matter. LivaNova is committed to provide quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,



i.V. Christian Peis
Director Quality Assurance

Enclosed:

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

Attachment 1 Affected Product List

FIELD SAFETY NOTICE

9611109-06/21/16-004-C

Product Code	Product description	Affected Serial Number range
16-02-50	Heater-cooler 1T, 230V	16S00808 - 16S02268
16-02-80	Heater-cooler 3T, 230V	16S10027 - 16S15641
16-02-81	Heater-cooler 3T, 240V	16S10743 - 16S11708
16-02-82	Heater-cooler 3T, 208V	16S10772 - 16S15523
16-02-83	Heater-cooler 3T, 127V	16S11455 - 16S15190
16-02-85	Heater-cooler 3T, 120V	16S10958 - 16S15634
16-02-95	Heater-cooler 3T, 200V	16S12004 - 16S15385
16-70-00	FlexTherm device	16E01000 – 16E01120

Please refer to Attachment 2 for affected Systems at your site.

Attachment 2 - Customer Response Form

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According to our records you have the following affected products:

<Fill in the customer related codes and serial numbers only- Use Attachment 4_Product trace list (Excel File)>

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form to:

Sorin Site/ Distributor Name: <<Print Your Company name here>>
 Country: <<Print Your Country here>>
 Contact Name: << Print Your Contact Name here>>
 E-mail: <<Print Your E-mail address here>>
 Fax No.: <<Print Your Fax No. here>>
 Phone Number: <<Print Your Phone No. here>>

Section 1 - Please Complete:

1. We HAVE reviewed and understand the attached Field Safety Notice yes no
2. We DO NOT understand the attached Field Safety Notice and request more information yes no

Please contact us:

Thank you for your cooperation in completing this Customer Response Form. Please return to Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

Customer Name: <<Print Your Company name here>>
 Country: <<Print Your Country here>>
 Contact Name: << Print Your Contact Name here>>
 E-mail: <<Print Your E-mail address here>>
 Fax No.: <<Print Your Fax No. here>>
 Phone Number: <<Print Your Phone No. here>>

Submitted by
 Signature
 Date/...../.....