

SORIN GROUP DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

August 6, 2015

Customer Name
Address
City, State Zip

Subject: Update to the Field Safety Notice for Heater-Cooler System 3T

Dear Valued Customer:

You recently received a Field Safety Notice from Sorin Group regarding the Heater-Cooler System 3T (Reference # 9611109-06/03/15-002-C, dated June 15, 2015).

The purpose of this Field Safety Notice was to:

- Remind you of the importance of following disinfection and maintenance procedures.
- Inform you that if your Heater-Cooler 3T is not properly maintained and it becomes contaminated, there is a possibility that bacteria can be aerosolized when the device is operated serving as a potential source for contamination.
- Provide you with updated instructions for use regarding disinfection and maintenance procedures.

This letter is to inform you that the Heater-Cooler System 3T Operating Instructions provided with the Field Safety Notice dated June 15, 2015 were intended for distribution to English speaking countries in the European Union (EU) rather than for the United States.

Although the EU and USA cleaning and disinfection procedures are equivalent, the EU procedure includes additional chemicals only available in other countries. Additionally, the USA Operating Instructions include information specific to the U.S. such as English units of measure and an Indications for Use statement.

The USA Heater-Cooler System 3T Operating Instructions are attached to this letter.

For your convenience, the USA Heater-Cooler System 3T Operating Instructions are available on the Sorin Group website at www.sorin.com/3t . They can be viewed, saved or printed as you prefer.

Customer Actions:

- Please discard all existing Heater-Cooler System 3T Operating Instructions and replace them with the attached USA Heater-Cooler System 3T Operating Instructions.
Note: The current USA Heater-Cooler System 3T Operating Instructions are CP_IFU_16-XX-XX_USA_014. This identification number is printed at the bottom of each page.
- Follow the actions detailed in the Heater-Cooler System 3T Field Safety Notice dated June 15, 2015.
- Please complete and return the attached Customer Response Form by fax to 303-467-6502 or by email to USFSN@sorin.com.

Contact Information:

Please contact your Sorin Group account representative if you have any questions. If further assistance is required, please contact:

Technical Services hotline at 1-800-221-7943, extension 6355

For your reference, we have also created a list of Frequently Asked Questions, Quick Start Instructions and a 3T Disinfection Video on our website at www.sorin.com/3t.

Sorin Group is committed to providing quality products and services. Thank you for your cooperation in this matter. This information will also be provided to the FDA.

Sincerely,



Christian Peis
Director Quality Assurance

Attachment 1: Affected Products List

Attachment 2: Customer Response Form

Attachment 3: USA Heater-Cooler System 3T Operating Instructions

ATTACHMENT 1

Affected Product List

UPDATE TO THE FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C

Product Code	Product description	Affected Serial Number range
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

Please note, all Sorin Heater-Cooler System 3T Devices are affected. Refer to the Customer Response Form for your affected products.

ATTACHMENT 2

Customer Response Form

UPDATE TO THE FIELD SAFETY NOTICE

Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices
Reference # 9611109-06/03/15-002-C
Including USA Heater-Cooler 3T System Operating Instructions

According to our records you have the following affected products:

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

Please return this completed form: By fax to 303-467-6502 or by email to USFSN@sorin.com.

Section 1 - Please Complete this section:

- We HAVE reviewed and understand this Field Safety Notice Yes No
- WE HAVE implemented the proper Operating Instructions Yes No

Customer Name: _____
Contact Name: _____
E-mail: _____
Fax No.: _____
Phone Number: _____

Submitted by _____

Signature _____ Date _____/_____/_____

ATTACHMENT 3

USA Heater-Cooler System 3T Operating Instructions

UPDATE TO THE FIELD SAFETY NOTICE