
URGENT FIELD SAFETY NOTICE

Important Update to User Instructions For Sorin Group Italia Manufactured Oxygenators

Affected Devices: Apex, adult oxygenator / Apex HP, adult oxygenator / Avant, adult oxygenator / Compactflo Evolution, adult oxygenator / Eos, paediatric and small adult oxygenator / Eos ECMO, paediatric and small adult oxygenator / ECC.O, extracorporeal circulation optimized / ECC.O 5, extracorporeal circulation optimized / Primo2x, adult oxygenator / Synergy, adult oxygenator / Synthesis, adult oxygenator / Synthesis 4D, adult oxygenator

Type of Action: Field Safety Corrective Action – Important User Instructions

Date: 29 November 2011

Manufacturer Ref.: FSCA02-11

Attention: Risk / Safety Managers, Distributors, Clinicians, Perfusionists, Nursing Staff and other users of the above mentioned medical device.

Details on

Affected Devices: All listed oxygenators and all Perfusion Tubing Systems containing these oxygenators.

Dear Valued Customer:

Sorin Group Italia has received customer complaints reporting a leak between the blood and water compartments of the heat exchanger used in the referenced oxygenators. The occurrence rate has been extremely low (less than 0.002%) and to date there have been no reports of any associated patient injuries. Should a leak occur between the blood and water compartments, it may lead to infection and/or damage to the blood, and could contaminate the water within the heater-cooler equipment used for the procedure.

Our investigation has determined that prolonged contact with sodium chloride (NaCl) could cause micro holes in the heat exchanger of the referenced oxygenators. Sodium chloride (NaCl) is commonly used in priming solutions.

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Cap. Soc. € 8.479.240,00 - Cod. Fisc. 10556980158
Part. IVA 02109510368 - ISO Code IT 02109510368
R.E.A. Milano n. 1767776
Reg. Imp. Milano n. 10556980158

To minimize risk and clarify priming procedures for the use of our products, we are adding the following to the Instructions for Use:

WARNING:

- **Minimize the time the device is in contact with priming solutions. Exceeding 24 hours can cause a leak between the blood and water compartments of the heat exchanger.**
- **A leak between the blood and water compartments of the heat exchanger may result in infection and/or damage to the blood.**

Requested Actions:

1. Communicate this new warning information to all personnel involved in the use of the referenced products. If you have distributed the referenced products to a third party, please forward this important information to them.
2. Complete and return the Customer Confirmation Form to acknowledge that you have received and understood this communication. Please return the completed form by fax or by email to your Sorin Group contact person.

If you have any questions regarding the attached Customer Confirmation Form, please contact to your Sorin Group representative

Sorin Group is committed to providing quality products and service to its customers. Thank you for your kind cooperation and please accept our apologies for any inconvenience caused in this matter.


Vincenzo Silvestri,
Manager, Industrial Quality Assurance
Sorin Group Italia
Cardiopulmonary BU

Attachment: Customer Response Form

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