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August 8, 2017

Dear Valued Customer,

On June 30, 2017, LivaNova issued an Urgent Medical Device Correction regarding the 3T Heater Cooler Systems when used with oxygenators that may not be compatible, e.g., certain polymer-based heat exchangers.

The LivaNova Correction states, "LivaNova has become aware that plastic heat exchanger fibers separating the blood compartment from the water compartment in certain oxygenators may allow diffusion of hydrogen peroxide in a quantity that exceeds the allowable limits (ALs) defined by the company."

Terumo Cardiovascular Systems Corporation assures you that all Terumo Capiox® oxygenators and cardioplegia sets utilize the highest quality stainless-steel heat exchangers. Through testing, Terumo Cardiovascular Systems has verified that stainless-steel prevents diffusion of hydrogen peroxide from the heater cooler water into the patient's blood.

Additionally, the correction states, "The 3T Operating Instructions prescribe the addition of 150mL of medical grade 3% hydrogen peroxide (H₂O₂) 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 as defined in the 3T Operating Instructions."

Terumo Cardiovascular Systems has taken proactive measures to assess the compatibility of its disposable products that come into contact with 3% hydrogen peroxide solution. Terumo assures users that the disposable products listed below are compatible for use during CPB procedures when the 3T Heater Cooler System and 3% hydrogen peroxide solution are used in parallel. The list of compatible products includes:

- All CAPIOX brand oxygenators
- CAPIOX CP50 cardioplegia sets
- Sarns™ conductor heat exchanger

If you have any additional questions or concerns related to this matter, please contact your local Terumo sales representative.

Yours truly,

A handwritten signature in black ink, appearing to read "Adam Pickholtz".

Adam Pickholtz
Manager, Regulatory Affairs
Terumo Cardiovascular Systems Corp.