Chief Executive Officer
The Royal Children’s Hospital
50 Flemington Road
Parkville
VIC, 3052

Attention: 1. Perfusion Department
2. Director of Nursing

URGENT MEDICAL DEVICE SAFETY ALERT

Product Name: Medos Heater/Cooler
Catalogue Number: ME DPHC 0001 ARTG Number: 262576
TGA Ref: RC-2017-RN-00512-1

Lovell Surgical Supplies International Pty Ltd, following advice from Medos (Xenios AG), and following consultation with the Therapeutic Goods Administration (TGA), is issuing this Safety Alert for the above-mentioned product.

This medical device is intended for cooling or heating water circulating through the heat exchanger of a membrane oxygenator during extracorporeal bypass. The device is not to be used for cardiopulmonary bypass associated with open cardiothoracic surgery.

In response to local and international concerns of contamination within other Heater/Cooler units, Medos are currently validating a new disinfection protocol which we will make available as soon as possible.

No reported incidents of patient infection with Nontuberculous Mycobacterium (NTM) associated with the use of the Medos Heater/Cooler have been reported to Medos, and because this is a 'closed system', Medos is confident that the risk to the patient remains low due to the design of this system.

The NTM Mycobacteria chimera is known to be present in water, and the environment in general, and there is potential for the contamination source to be from the environment itself.

Long Term Corrective Actions
Medos are currently validating a more effective cleaning protocol, which will be included in an updated IFU that will be introduced via a Recall for Product Correction, once all of the relevant testing has been completed.
Lovell Surgical Supplies International Pty Ltd will then issue each customer with the updated Instructions For Use, at that time.

Possible Mitigations representing case-by-case precautionary considerations for Users and/or Hospital Infection Control Committees include:

1. The maximum stated concentration of the disinfectant as stated in the interim guide could be used for each routine disinfection process until further notice. Alternatively, Sanosil S010 or S015 (5% or 7.5% H2O2), undiluted may be used provided the tank is not closed for the disinfection procedure;

2. Where not covered by existing procedures, and as recommended in the instructions for use and attached interim guide, staff should thoroughly wash hands and use a suitable set of disposable gloves and apron to minimise the likelihood of inadvertently contaminating the machine;

3. The shortest time interval between disinfections as stated in the current IFU could potentially be adopted as routine until further notice;

4. The maximum contact time for the disinfection cycle as stated in the current IFU could be adopted as routine until further notice;

5. The use of physical service tags indicating the time, date and type of disinfection process carried out on each machine along with a scheduled due date for the next disinfection could be utilised;

6. Where not covered by existing procedures, a routine or an escalated regime of scheduled microbiological testing of the water in each machine could be conducted and the results maintained in a dedicated machine log; and

7. Individualised considerations as to how the machines are stored should be conducted and applied.

The Cleaning & Disinfection Interim Guide accompanying this Safety Alert is different from the current IFU Section 7 Cleaning and Disinfecting in the following main ways:

Changing the water - Filling the unit:

- Add approx. 1 litre of distilled water to the water tank of the unit, e.g. with a funnel.
- We recommend using a sieve to prevent foreign material entering the water circuit.
- Watch the water level indicator during filling. The water level should be just under the MAX mark after filling.
• Screw the cap on the water filler tightly until it is sealed.

Disinfecting the water circuit:
• Drain the system as described in "Changing the water".
• Add 1 liter of 5% or 7.5% H2O2 Sanosil concentrate.
• Fill the unit to the maximum fill level (see “Filling the unit”) with the H2O2 mixture.
• Leave the tank lid open during cleaning to prevent overpressure.
• Close off the bypass hose by connecting the ends of the water hoses together with an adapter piece.
• Switch on the unit at 25 °C and let it run for 15 minutes. Then increase the temperature to 40 °C for another 15 minutes.

Mains water can be used for operation of the unit. The service life of unit parts in contact with water will be reduced depending on the quality and hardness of the water. However, during disinfection flocculation of the silver content may occur, therefore we recommend using demineralized/distilled water for mixing with Sanosil.

Actions to be taken by User:
• Thoroughly review the information contained in the Interim Cleaning and Disinfection Guide;
• Complete and return the enclosed acknowledgement form as soon as possible;
• Please inform all relevant staff;
• Users should assess the risk Vs benefit balance of continuing to use the Medos Heater/Cooler on a patient by patient basis;
• This Safety Alert, accompanied by the Interim Cleaning and Disinfection Guide, as well as the range of possible mitigations given above, is to be considered in conjunction with the current Approved IFU (disregarding the cleaning instructions in section 7) on a case-by-case basis, in consultation with the relevant Hospital staff and/or committees; and
• Continue to monitor the contamination levels, where there is a positive culture, the product should be decontaminated, and the product re-tested. If after decontamination, there continues to be a positive culture, the product should be removed from use, and reported to Lovell Surgical Supplies International Pty Ltd.
In the event this device has been supplied on to any other organisations, please provide Lovell Surgical Supplies International Pty Ltd with this information and provide these organisations with a copy of this letter within 24 hours on +61 (0)3 9775 1855.

This Safety Alert should be prominently displayed in a location frequented by staff until such time as the IFU for the Medos Heater/Cooler has been updated to provide a more effective cleaning protocol effective against NTM potential contamination. Lovell Surgical Supplies International Pty Ltd and Medos AG sincerely regrets any inconvenience caused to your hospital.

Yours Sincerely

Luke Smith
Managing Director
7th July, 2017
Facsimile Reply Form

To: Lovell Surgical Supplies International Pty Ltd
Attention: Luke Smith
Facsimile Number: 03 9775 1414
Subject: Urgent Medical Device Safety Alert – Medos Heater Cooler Unit

From: ______________________________________________
(name of institution)

Contact Person: _______________________________________
(please print)

Telephone Number: ____________________________________

Facsimile Number: ____________________________________

□ We do not have a Medos Heater Cooler Unit at our site
□ We do have a Medos Heater Cooler Unit at our site and agree to follow the new disinfection procedures:

Serial #:__________ Serial #:__________

Serial #:__________ Serial #:__________

Serial #:__________ Serial #:__________

Any other relevant details:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Signature: __________________________________________

Date: ____________________