URGENT MEDICAL DEVICE SAFETY ALERT

Product Name: ParaTherm Heater/Cooler

Catalogue Number: 540001 ARTG Number: 278698

TGA Ref: RC-2017-RN-00453-1

Australian Blood Management Unit Trust, following advice from Chalice Medical Ltd. 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.

Chalice have received several isolated reports confirming that Nontuberculous Mycobacterium (NTM) bacterial contamination has been found within the ParaTherm Heater/Cooler unit itself. None of these reports have resulted in any patient infection.

In response to this and in recognising the specific patient safety concerns regarding NTM (specifically Mycobacterium chimaera) contamination of heater/coolers, particularly those used in open-heart surgery (which is not an indication for the ParaTherm Heater/Cooler), we have carried out a full review of the cleaning protocol within our current Instructions for Use (IFU). We are now aware that the cleaning protocol recommended in our IFU is not successful at killing a sufficient number of the NTM strain of bacteria.

We are currently validating a new disinfection protocol which we will make available as soon as possible.
No reported incidents of patient infection with NTM associated with the use of the ParaTherm Heater/Cooler have been reported to Chalice Medical Ltd., and because this is a 'closed system', we are confident that the risk to the patient remains low due to the design of this system.

The NTM *Mycobacteria chimaera* 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**

We 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.

We 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\(^1\) could be used for each routine disinfection process until further notice;
2. Where not covered by existing procedures, 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. Where a range is given, 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.
**Actions to be taken by User:**

- Thoroughly review the information contained in the Interim Cleaning and Disinfection Guide;¹
- 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 ParaTherm 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 Australian Blood Management Unit Trust.

In the event this device has been supplied on to any other organisations, please provide Australian Blood Management Unit Trust with this information and provide these organisations with a copy of this letter within 24 hours.

This Safety Alert should be prominently displayed in a location frequented by staff until such time as the IFU for the ParaTherm Heater/Cooler has been updated to provide a more effective cleaning protocol effective against NTM potential contamination.

Australian Blood Management Unit Trust and Chalice Medical Ltd sincerely regrets any inconvenience caused to your hospital.

Hayden Dando  
Australian Blood Management Unit Trust  
19th April 2017
The Interim Cleaning and Disinfection Guide accompanying this Safety Alert is different from the current IFU Section 7 Cleaning and Disinfecting in the following main ways:

- Use of a wipe or surface disinfection product approved by your hospital infection control department is now recommended and commonly used products are shown in Tables 1 and 2 of the interim guide.
- The Caution section advises the user to carefully follow the IFU and removes the option to use other processes once approved by the manufacturer.
- Removing the ParaTherm with the oxygenator still connected to a non-clinical area after each clinical use before disconnecting the water pipes to the oxygenator is now clearly recommended. A reminder to remove the ParaTherm to a non-clinical environment to top-up the water tank has been added to the Caution in Section 1.8.2.
- 100% of a 7.5% hydrogen peroxide ($\text{H}_2\text{O}_2$) cleaning agent (Sanosil S015) is now recommended instead of Sanosil S003. The cleaning protocol removes the steps to dilute the cleaning agent.
- During the required cleaning after each clinical use (Section 1.4), only half of the new higher strength cleaning agent (400mls) is added to the tank and the cap then screwed down before agitating the device. This is to improve contact of the cleaning agent with all of the internal water lines. When the remainder of the cleaning agent is then added to the water tank, the cap is not screwed down but placed instead over the water tank filler neck. This is because the cleaning agent contains a higher strength $\text{H}_2\text{O}_2$ which can result in a build-up of pressure over time. A Caution note is added to Section 1.4 stating this requirement and instructing the user to not overfill the ParaTherm. During clinical use, the cap must always be screwed down fully; it is only during cleaning with the concentrated 7.5% hydrogen peroxide ($\text{H}_2\text{O}_2$) cleaning agent that the cap should not be screwed down.
- When the device is not required for immediate clinical use (Section 1.5), the designated hoses should be disconnected, dried and stored with the ParaTherm in a clean, dry place. The device should continue to be cleaned at the stipulated cleaning intervals (every 14 days) even when not in use.
- Use of a thin film of silicon paste or Vaseline on the O-rings at least every 6 months has been removed and replaced with visual inspection and recommendation for if signs of cracks or damage are observed (Section 1.8).
- Advice to follow national recommended procedures for microbiological checks has been added in Section 1.8.1, together with a statement that, whilst the ParaTherm uses a closed system which should not result in aerosolisation of water when used in accordance with the IFU, there remains a residual risk that patient infection could still occur when using a contaminated device.
To: Australian Blood Management Unit Trust  
Attention: Hayden Dando  
Facsimile Number: 02 9475 4360  
Subject: Urgent Medical Device Safety Alert - ParaTherm Heater Cooler – ARTG 278698  

Name of Institution: ________________________________________________________  
Contact Person: _____________________________________________________________  
(Please print)  
Telephone Number: _________________________________________________________  
Facsimile Number: _________________________________________________________  
☐ We do not have a ParaTherm Heater Cooler Unit at our site  
☐ We do have a ParaTherm Heater Cooler Unit at our site and agree to follow the new disinfection procedures:  

Serial Number: ___________________________  
Serial Number: ___________________________  
Serial Number: ___________________________  
Serial Number: ___________________________  
Any other details: ____________________________________________________________  
_________________________________________________________________________  

Signature: ___________________________ Date: _____________________