

# Safety Notice

## Medical Devices

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### HEATER COOLER UNIT

#### Priority 2 – Warning

HPRA Safety Notice: SN2014(34)

Issue Date: 7th August 2014

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Various	V21361

#### ISSUE

Heater cooler devices that are used during open heart surgery to control the temperature of blood contain water/fluid. If this water/fluid is not properly managed and disinfected, microbial growth can occur in the device and over time a bio-film may form. Contamination of *Mycobacterium chimaera* has been identified in a small number of heater cooler devices in Switzerland and has been potentially linked to infections in patients some years after surgery.

#### ACTION OR RECOMMENDATIONS

The Health Products Regulatory Authority (HPRA) advises that users:

1. Ensure that all theatre staff are advised of the risks associated with microbial contamination of heater/cooler devices used during open heart surgery and the specific issue identified in Switzerland with *Mycobacterium chimaera*.
2. Review your procedures to ensure that you have appropriate water management in your theatres.
3. Review your heater/cooler operating practices and evaluate your device(s) for potential contamination.

4. Review the device operator's manual to assure that your practices are aligned with the directions.
5. If you are concerned about any of your devices, perform microbial sampling of the water/ fluid in your heater cooler; disinfect/decontaminate the device if necessary.
6. Forward this Safety Notice to all those that need to be aware within your organisation or to any organisation / person where these devices have been transferred. Please maintain an awareness of this notice for an appropriate time period.

## TARGET GROUPS

Hospital CEOs Medical Directors Hygiene Specialists, Theatre Managers Theatre Nurses Risk Managers Perfusionists Cardiac Surgeons	
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## BACKGROUND

An ongoing investigation by Swissmedic (the Competent Authority for Medical Devices in Switzerland), Swiss Federal Office of Public Health, Swissnoso and a Swiss hospital has identified that in rare cases, infections have been observed in patients that resulted in illness some years after cardiac surgery. The infections are believed to be due to the presence of the slow growing *Mycobacterium chimaera* in cardiac surgery theatres which may be a potential risk for cardiac surgery patients. These organisms are found in water, including tap water sources.

As part of this investigation it has been identified that the heater cooler devices, in some of the Swiss hospitals, that are used during open heart surgery to control the temperature of the blood are contaminated with *Mycobacterium chimaera*. If water/ fluid that is used in these devices is not properly managed / disinfected, microbiological growth can occur within the device and over time a bio-film may form.

## HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority	Telephone:	+353-1-6764971
Kevin O'Malley House	Fax:	+353-1-6344033
Earlsfort Centre	E-mail:	<a href="mailto:devicesafety@hpra.ie">devicesafety@hpra.ie</a>
Earlsfort Terrace	Website:	<a href="http://www.hpra.ie">www.hpra.ie</a>
Dublin 2		