

## **Mycobacterial Infections Associated with Heater/Cooler Units in Cardiac Surgery**

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Objective: Delegates will learn about the proposed risk of using heater/cooler units in cardiac surgery, with an in-depth look at the science, patient risk, and regulatory and international perspectives.

In 2015 the Perfusion community was made aware that the heater cooler units that we use on a daily basis were implicated in adverse outcomes for our patients. A mycobacterium, *m.chimaera*, was thought to be contaminating the heater cooler units. On October 15, 2016 the Federal Drug Administration (FDA) issued [Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices – Safety Communication](#) recommendation to minimize patient exposure. On June 1<sup>st</sup> the FDA issued a second communication [Mycobacterium chimaera Infections Associated with Sorin Group Deutschland GmbH Stöckert 3T Heater-Cooler System- Safety Communication](#) to provide new information and recommendations about *Mycobacterium chimaera* infections. On June 2-3, 2016 the FDA held a meeting to seek expert input into the heater cooler contamination, associated infections and to develop mitigation strategies. The discussion and resolutions from that meeting are available at

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm485091.htm>

In this session we will share some of the information presented to the FDA panel and have the opportunity to ask questions. Some of the questions you may like the panel to address may include:

### Testing

*In the clinical environment, should monitoring (i.e. surveillance) of the HCD water for NTM or bacterial contamination be performed?*

*Can every laboratory test for Mycobacterium chimaera, where should I send my test samples?*

*How often should we schedule testing for these units?*

*After the initial test, how often do units need to be tested?*

### Maintenance

*What are health services' responsibilities around maintenance and cleaning of heater cooler units?*

*What maintenance records and microbiological sampling results need to be kept by health services?*

*When should health services start recording information on unit use in patient medical records (for traceability purposes)?*

*Should cleaning/disinfection servicing performed by the manufacturer be part of routine maintenance to demonstrate an acceptable level of contamination. If so, at what frequency?*

*If contaminated*

*What should health services do if all heater cooler units are contaminated?*

*Should heater cooler units be moved outside of the operating theatre?*

*What are the potential impacts on surgical services?*

*How do I decontaminate my heater cooler?*

*Patients*

*What information should be provided to patients before cardiac surgery?*

*How should health services manage patients that present with post-operative infection after cardiac*

*surgery?*

*If test results are positive, should a retrospective review of all cases be performed?*