[High Priority] - A24543 : Various Heater-Coolers Used With Cardiopulmonary Bypass Machines: May Become Contaminated with Mycobacterium, Potentially Leading to Patient Infection

Medical Device Ongoing Action

Published: Thursday, June 11, 2015

UMDNS Terms:

- Heart-Lung Bypass Units [11969]
- Warming/Cooling Units, Patient [12068]

Product Identifier:
Various Heater-Coolers Used With Cardiopulmonary Bypass Machines *[Capital Equipment]*

Geographic Regions: U.K.

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Infection Control, OR/Surgery, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement

Problem: The U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a Medical Device Alert (MDA/2015/022) warning healthcare workers that a small number of patients underwent cardiac surgery with cardiopulmonary bypass and developed endocarditis and/or septicemia associated with *Mycobacterium avium (M. avium*) species. MHRA also states that a study suggests that the possible source of the *M. avium* is colonization by bacteria in the water used in heater-coolers. The original report and updates can be found on Public Health England's website. MHRA also states that the overall infection risk is difficult to quantify because current practices for monitoring an operating room's environmental integrity may not identify this slow-growing, resistant organism. The manufacturers have not confirmed the information provided in the source material.

Action Needed:
MRHA recommends that you do the following:

- Follow the manufacturer's instructions for use (IFU) at all times, especially when cleaning and disinfecting affected product and sterile components.
- Review, update, and follow local protocols for water management practices, water quality, environmental hygiene, vigilance, and device maintenance of affected product.
- Review, update, and follow local risk assessments for the safe operation of heater-coolers.
- Identify whether there are any practices that could lead to transmission of organisms through aerosolization where there is water contact with other cardiac surgery equipment.
- Have systems in place to notify the manufacturer and MHRA if you observe specific risks with any affected product.
- Have systems in place to contact Public Health England (PHE) , or the respective health protection agencies of devolved administrations, if you have new cases of *Mycobacteria* infections.
- Report any adverse incidents to MHRA through the Yellow Card scheme .

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Inquiries to MHRA should cite reference no. MDA/2015/022 or 2014/007/016/081/003.

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Heater-cooler devices used in cardiac surgery—risk of infection with *Mycobacterium* species [online]. London: Department of Health; 2015 Jun 11 [cited 2015 Jun 11]. (Medical device alert; no. MDA/2015/022). Available from Internet: Click here .

Comments:

- For information on a previous action by Sorin regarding *Mycobacteria* contamination in Heater-Cooler devices, see Alert Accession No. A22770 .

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Source(s):

- 2015 Jun 11. MHRA MDA. MDA/2015/022 Download

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