3T MEDICAL SYSTEMS

Altrix™ Precision Temperature Management System

Disinfection and aerosolization **validation**

Overview

Since October 2015, the FDA issued three safety communications regarding a potential association between patient infections and water-based heater-cooler devices, primarily in patients undergoing cardiothoracic surgical procedures.[1-4] Since Altrix uses a water-based system to heat and cool patients, Altrix is within the scope of the safety communications. Although the water circulating within those devices did not directly contact patients, nontuberculous mycobacteria (NTM) might have aerosolized into the operating room and caused serious illness and death.[1-4] Global regulatory agencies continue to investigate and monitor the situation.

How we addressed the issue

Rigorous tests were developed to evaluate the risk of microbial aerosolization with testing performed by an independent laboratory. These tests verified Altrix, when used and maintained according to manufacturer instructions, does not aerosolize microbes from its water system. In addition, internal and external disinfection protocols (using guidance from the Association for the Advancement of Medical Instrumentation Technical Information Report) were developed to further reduce the risk of contamination. Finally, we complete a disinfection protocol as a final step to the manufacturing process of Altrix to ensure each device is disinfected prior to customer delivery.

Validation summary

- ✓ Aerosolization: Altrix does not aerosolize microbes from its water system.
- ✓ Air filtration: A 0.2 μm filter prevents microbes from escaping into the environment.
- ✓ Cleaning and disinfection:
  - Disinfection of the Altrix internal water system was validated using *M. mucogenicum*
  - Human factors studies concluded the internal and external cleaning and disinfection procedures detailed in the IFU are easy to follow.

FAQs

What type of clearance or certification has Altrix received?

Altrix was cleared by the FDA via the 510(k) premarket notification process. The FDA reviewed pertinent test data, including aerosolization, air filtration, labeling, and cleaning and disinfection to support its clearance. The Altrix 510(k) clearance number is K152266.

What is the scope of devices affected by the safety communications?

The ECDC and FDA published safety communications regarding nontuberculous mycobacterium (NTM) infections.[1-4] The safety communications included three types of water-based heater-cooler devices that provide heated and/or cooled water to 1) oxygenator heat exchangers, 2) cardioplegia (paralysis of the heart) heat exchangers, and/or 3) warming/cooling blankets. Since Altrix uses a water-based system to heat and cool patients, Altrix is within the scope of the safety communications. It is important to note that issues identified by FDA in its safety communications to date have primarily occurred with water-based heater-cooler devices used during cardiothoracic surgeries.

What is NTM?

Nontuberculous mycobacteria, otherwise known as NTM, are organisms naturally found in soil or water. Mycobacterium chimaera (*M. chimaera*), the slow-growing type of NTM implicated in these cases,[4,5] may cause serious infection or death especially in immunocompromised patients. The FDA believes *M. chimaera* infections associated with heater-cooler devices. However, they are difficult to detect because infected patients may not develop symptoms or signs of infection for months to years after initial exposure.[2,5]

What is the customer's responsibility to maintain a safe and effective device?

The customer must strictly follow the cleaning, disinfection, and general maintenance requirements detailed within Altrix's Instructions for Use, including disinfection of each device prior to initial use. During a recent FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee, a panel of experts considered end user adherence to the manufacturer's Instructions for Use to be a key factor in helping to mitigate the risk associated with the water-based heater cooler devices.[6]

References

1. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm
2. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm
3. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm
4. http://ecdc.europa.eu/en/press/news/_layouts/forms/News_DispForm.aspx?List=8db7286c-fe2d-476c-9133-18ff4cb1b568&ID=1209
5. Haller S, Höller C, Jacobshagen A, Hamouda O, Abu Sin M, Monnet DL, Plachouras D, Eckmanns T. Contamination during production of heater-cooler units by Mycobacterium chimaera potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016. Euro Surveill. 2016;21(17):pii=30215.
6. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM503711.pdf
7. https://www.cdc.gov/media/pressrel/2010/r100714.htm

As with any medical device, there are risks associated with use of the Altrix Precision Temperature Management System. Read and strictly follow the instructions for use, including information regarding indications for use, warnings, precautions, methods of use, and device maintenance.

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