October 13, 2016

Dear Colleagues:

The Centers for Disease Control and Prevention (CDC), in collaboration with National Jewish Health, has identified additional laboratory information in its ongoing investigation into heater-cooler units used during open-chest cardiac surgery. The new laboratory findings demonstrate that the Stöckert 3T heater-cooler devices manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH) linked to outbreaks in several states, were likely contaminated during the manufacturing process. These units represent about 60 percent of the heater-cooler devices currently in use in the United States, and may be putting patients at risk for severe infection from slow-growing bacteria known as *Mycobacterium* *chimaera*.

**CDC is advising hospitals to alert clinicians and patients of this risk and advise patients to seek immediate medical care if they have had open-chest cardiac surgery and are experiencing symptoms such as night sweats, muscle aches, weight loss, fatigue, or unexplained fever.**

Infections with *Mycobacterium* *chimaera,* a species of nontuberculous mycobacterium (NTM), can be challenging to diagnose and treat. The bacteria are slow-growing and patients may not experience symptoms for months or even years after surgery. Clinicians and patients may not immediately consider an NTM infection when symptoms present. Delayed diagnosis may make treating these infections even more challenging. There is no test to determine whether a person has been exposed to the bacteria. Infections can be diagnosed by detecting the bacteria by laboratory culture; the slow growing nature of the bacteria can require up to two months to rule out infection.

**As CDC’s valued healthcare partner, we are sharing the attached clinician & patient notification toolkit to aide in alerting clinicians and patients about the risk of infection from these heater-cooler units.**

Attached you will find:

* Modifiable patient notification letter
* Letter to alert clinicians
* Letter for patients to take to their healthcare provider
* Questions and answers document

These materials can be customized by healthcare facilities and/or health departments and are designed to be sent directly to clinicians and patients. CDC will make updates to these materials as additional information becomes available.

Sincerely,

Centers for Disease Control and Prevention

Division of Healthcare Quality Promotion

**Additional Resources:**

* Link to Sorin 3T Website: <http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t>
* CDC Website: <https://www.cdc.gov/hai/outbreaks/heater-cooler.html>
* CDC MMWR: [Mycobacterium chimaera Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States](https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w) - <https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w>
* CDC Health Alert Notification: CDC Advises Hospitals to Alert Patients at Risk from Contaminated Heater-Cooler Devices Used during Cardiac Surgery - <https://emergency.cdc.gov/han/han00397.asp>
* FDA Safety Alert: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/UCM520191.htm>