

# F.A.Q.

## Frequently Asked Questions for Cardiac Surgery Patients Regarding CDC Warning Infection Risk

The Centers for Disease Control and Prevention (CDC) is warning healthcare providers – including Maine Medical Center – and patients about the potential risk of infection from certain devices used during open-heart (open-chest) surgery.

Patients who have had open heart surgery should seek medical care if they are experiencing symptoms associated with Nontuberculous mycobacteria (NTM) infections, such as night sweats, muscle aches, weight loss, fatigue, or unexplained fever. This advice follows new information indicating that some LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler devices, used during many open-heart surgeries, might have been contaminated during manufacturing, which could put patients at risk for infections.

Maine Medical Center, with the help of the Centers for Disease Control, has developed the following Frequently Asked Questions (FAQs) for patients and families who have had open heart surgery at MMC during the affected period.

***Q. I've had open heart surgery at Maine Medical Center. Does this warning include me?***

A. The CDC's warning of potential risk only applies to patients who have undergone open-heart (chest) surgeries since Jan. 1, 2012. MMC is notifying individual patients with letters who have had specific procedures during this time period.

***Q. What is the risk of infection?***

A. Overall, the risk is thought to be very low. Maine Medical Center has zero (0) identified cases.

***Q. How long does it usually take for these infections to show up?***

A. Nontuberculous mycobacteria (NTM) are slow-growing bacteria, and infections may take months to develop. Cases associated with this device have been diagnosed within months and up to several years after an open-heart surgery involving heater-cooler unit exposure.

***Q. Can a person who develops one of these NTM infections spread it to others, such as family members?***

A. No, the bacteria cannot be spread to others from an infected patient. Also, it is important to keep in mind that NTM is common in soil and water but rarely makes healthy people sick.



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***Q. Should everyone who was exposed to these devices during open-heart surgery receive antibiotics just in case?***

A. The risk that patients will develop an infection following exposure to a contaminated heater-cooler unit is very low. Antibiotics put patients at risk for allergic reactions and other side effects. Antibiotic use is also a key driver of antibiotic resistance, which can put patients at risk for antibiotic-resistant infections later.

***Q. How long does it take to find out if an infection is being caused by NTM?***

A. *M. chimaera* is a slow-growing species of NTM that can take eight weeks and sometimes longer to grow and allow final identification.

***Q. Why are these infections concerning?***

Symptoms of infection can take months to develop, and are often general and nonspecific. As a result, diagnosis of these infections can be missed or delayed, sometimes for years, making these infections more difficult to treat. Clinicians may not immediately consider an NTM diagnosis. Delayed diagnosis can result in more widespread disease in a patient. This, combined with underlying health problems such as heart disease can make these infections difficult to treat.

***Q. How do you think the devices got contaminated?***

A. NTM is common in water and soil. Recent CDC findings are consistent with previous reports suggesting that the heater-cooler units were contaminated during production. Testing conducted by the manufacturer in August of 2014 found *M. chimaera* contamination on the production line and water supply at the 3T manufacturing facility.

***Q. Have these devices ever been recalled? Why aren't they being recalled now?***

A. In 2015, the manufacturer recalled the instructions for use, but not the device itself. These kinds of heater-cooler devices are critical for life-saving surgery.

***Q. What is Maine Medical Center doing to mitigate the risk?***

A. Maine Medical Center has tested the devices repeatedly, finding no evidence of the bacteria that has the CDC concerned. The device manufacturer has issued new protocols for cleaning the machine intended to mitigate any risk, and we are following those protocols as well continuing to rigorously test and inspect the equipment.

***Q: What should I do if I have additional questions or think I am exhibiting symptoms?***

A: If you have had open-heart surgery and have additional questions or are concerned about symptoms you may be experiencing, please contact your primary care provider or cardiologist and provide the letter you received from Maine Medical Center. You can additionally contact your cardiac surgeon.