

**URGENT UPDATE ON SORIN STOCKERT 3T HEATER/COOLER DEVICES
as of November 16, 2016**

Last week, I contacted you to alert you to a Centers for Disease Control (CDC) Health Advisory and Food & Drug Administration (FDA) Safety Communication that announced that the Stöckert 3T heater/cooler devices by LivaNova PLC (formerly the Sorin Group) may have been contaminated with *Mycobacterium chimaera* (*M.Chimaera*), a rare type of nontuberculous mycobacterium (NTM), during manufacturing.

This is an update to that communication, which included a list of your patients who underwent a surgical procedure with cardiopulmonary bypass (CPB) at the University of Michigan involving use of a Sorin Stöckert 3T heater/cooler devices in the past five years (when we had the devices at UM). We will be sending letters to all University of Michigan patients who may be at risk.

Since our initial communication, we have identified one patient who has developed this infection among the nearly 7,000 patients at the University of Michigan Health System who had surgery potentially using the Sorin Stockert devices.

The CDC estimates the risk to be less than 1 percent. We no longer use the heater/cooler devices associated with NTM infections, the Stöckert 3T devices, effective August 2016.

The CDC recommends clinicians, including cardiologists and general practitioners who take care of cardiac, general thoracic, vascular surgery (or other patients who had CPB during a procedure) before and after their surgery, be aware of the risk and consider NTM as a potential cause of unexplained chronic illness.

Infections can take months to years after surgery to develop, and symptoms are often general and nonspecific. As a result, diagnosis of these infections is often missed or delayed, making these infections especially difficult to treat. **Please see the attached fact sheet for detailed information on NTM infections. For more information and updates, visit <http://umhealth.me/2eml7K8> or <https://www.cdc.gov/hai/outbreaks/heater-cooler.html>.**

If you have a clinical question pertaining to one of your patients, or if you have a symptomatic patient who requires additional evaluation for potential NTM infection, please call M-LINE at (800) 962-3555 or internally at 936-3856 (24x7) to speak to one of our designated providers who can answer your heater-cooler related questions.

We have also established a hotline for patients who may call us directly at 855-336-5900. Representatives are available Monday through Friday from 8 a.m. to 5 p.m.

Sincerely,

Jeffrey S. Desmond, M.D.
Chief Medical Officer
University of Michigan Health System