



Dear Patient:

Please provide this letter to your primary care provider. Thank you.

Dear Healthcare Provider:

NYU Hospitals Center is notifying providers of recent findings from Centers for Disease Control and Prevention (CDC), in collaboration with National Jewish Health, regarding patients who have undergone open-chest cardiac surgery. Heater-cooler devices used during certain major surgeries that require the use of a heart/lung bypass machine have recently been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a slow-growing species of nontuberculous mycobacteria (NTM). Investigations into several clusters of infections linked to exposures to LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler devices during cardiac bypass surgery have determined that these devices were likely contaminated with *M. chimaera* during manufacturing. For patients who have had one of these surgeries, the chances of getting this infection are very low. The CDC estimates the risk to be less than 1 percent.

CDC is recommending that clinicians, including cardiologists and general practitioners who take care of cardiac surgery patients before and after their surgery, be aware of the risk and consider NTM as a potential cause of unexplained chronic illness. The CDC website which provides further details is www.cdc.gov/hai/outbreaks/heater-cooler.html

Symptoms of an NTM infection may include:

- night sweats
- muscle aches
- weight loss
- fatigue
- unexplained fever

Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations. Common examples include endocarditis, surgical site infection, or abscess and bacteremia. Other clinical manifestations have included hepatitis, renal insufficiency, splenomegaly, pancytopenia, and osteomyelitis. Patients have also presented with granulomatous disease which can imitate sarcoidosis.

M. chimaera 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.

We are working with the New York State Department of Health to guide our response, and will continue to partner with CDC and FDA to ensure we are following all safety recommendations. We have sent letters to all patients who underwent cardiac surgery utilizing these devices. We also established a dedicated toll-free telephone number staffed by registered nurses who will answer questions, screen for symptoms and if indicated, assist patients who may need further medical evaluation with scheduling an appointment with one of our providers at no cost to them. We believe that with our current practices we can continue to provide patients who need this device with safe, high-quality care.

In our letter to patients, we encourage them to discuss any symptoms with their primary care physician. If you have a clinical question pertaining to one of your patients or a symptomatic patient who requires additional evaluation for potential NTM infection, please call the toll free hotline 877-987-5633 (Monday through Friday from 8am to 6pm, ET) and identify yourself as a provider. You will be routed to the appropriate provider for a return call. Thank you for partnering with us to ensure patient safety.

Sincerely,

Fritz Francois, MD
Chief Medical Officer