

Carolinas HealthCare System

Dear Healthcare Provider:

Recently, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have noted a number of patients nationwide who have developed a rare bacterial infection that has been linked to exposures to LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler machines used during surgeries including open-heart, vascular and liver transplant surgeries.

Your patient has undergone a surgery where these heater-cooler machines were used either at Carolinas Medical Center, Carolinas Medical Center-Mercy, Carolinas HealthCare System Northeast or Carolinas HealthCare System Pineville. Your patient has been notified of the potential risk of developing this rare infection related to their surgery, and we encourage them to discuss any symptoms they are having with you, their healthcare provider. This rare infection is caused by *Mycobacterium chimaera*, a slow-growing species of nontuberculous mycobacteria (NTM).

The CDC is recommending that clinicians, including cardiologists and general practitioners who take care of these surgery patients before and after their surgery, be aware of the risk and consider NTM as a potential cause of unexplained chronic illness. *M. chimaera* are slow-growing bacteria and infections may take months or even years to cause symptoms.

Symptoms of an invasive NTM infection may include:

- Unexplained fever
- Night sweats
- Unexplained weight loss
- Fatigue
- Signs of surgical site infection such as redness or drainage from the surgical site

Patients with NTM infections following 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.

Clinicians and patients may not immediately consider an NTM infection when symptoms begin. 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.

When seeing patients with possible NTM infections and a history of either open-heart, vascular or liver transplant surgery, clinicians should consider arranging a consultation with an infectious disease specialist. If an NTM infection is suspected, it is important to obtain acid fast bacilli (AFB) cultures from an infected wound and/or blood to increase the likelihood of identification of the organism and to obtain an AFB smear in order to have preliminary information while awaiting culture results.

If you have a clinical question pertaining to possible nontuberculous mycobacterial infection related to surgery in one of your patients, or if you have a symptomatic patient who requires additional evaluation for potential NTM infection, please call our established hotline at (704) 512-5700.

Sincerely,

Carolinas Healthcare System