



Dear Sir or Madam,

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are conducting a nationwide investigation into reports that a device used to heat and cool a patient's blood during surgery has been linked to a very rare bacterial infection caused by *Mycobacterium chimaera*, a type of bacteria known as nontuberculous mycobacterium (NTM). Infections have been linked to the use of the LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler devices during cardiac bypass surgery. 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.

As recommended by the CDC, NYU Hospitals Center is notifying patients who have had open-chest surgery using the Stöckert 3T device, about the potential infection risk related to this surgery. We are contacting you today, because you or a member of your family has been identified in clinical records as a patient who has had open-heart surgery. We have performed more than three thousand open-chest procedures at NYU Hospitals Center since 2012. After a thorough investigation, we are aware of only two instances in which a patient of ours may have developed an infection related to Stöckert 3T heater-cooler device.

This type of infection is very slow growing, difficult to diagnose and it is possible to develop symptoms months to years after surgery. As such it is important to know the symptoms to look for, and to discuss any symptoms or questions you may have with your primary care doctor. We have included a letter you can take to your doctor to explain the situation. This infection cannot be spread person-to-person.

Symptoms of an NTM infection may include:

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

Please call 877-987-5633 toll free to discuss this situation, Monday through Friday from 8am to 6pm (Eastern Time). We will answer any questions you have, and if needed, schedule an appointment with one of our providers. You will not be charged any out of pocket expenses related to this appointment.

Sincerely,

Fritz Francois, M.D.  
Chief Medical Officer