



Beth Israel Deaconess
Medical Center



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

December 2, 2016

Mary Smith
115 Happy Lane
Joyville, USA 111223

Dear Mary,

We are writing to let you know about a potential infection risk linked to a device used during open-heart surgery. We are contacting you today out of an abundance of caution as our clinical records indicate that you are a cardiac surgery patient who might be affected.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are investigating reports that the Stöckert 3T Heater-Cooler System – a device used by hospitals across the nation to heat and cool the blood during surgery – has been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a type of bacteria known as nontuberculous mycobacterium (NTM).

We want to reassure you that the risk that you will be affected by this rare infection is very low – the CDC estimates the risk to be less than 1 percent. Beth Israel Deaconess Medical Center acted quickly after notification of this issue to eliminate the use of the Stöckert 3T Heater-Cooler System. We also want to reassure you that out of the thousands of patients who have had open-heart surgery at BIDMC, we are not aware of a single patient who has developed this infection.

The infection associated with this device is very slow-growing and can be difficult to diagnose. It cannot be spread from person-to-person. Symptoms can develop years after surgery, so it is important to know the symptoms to look for. Symptoms of this infection include:

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

We encourage you to discuss any symptoms or questions you may have with your primary care doctor and/or cardiologist.

We understand that you and your family may have additional questions or concerns. Beth Israel Deaconess Medical Center has established a special phone line to respond to your specific questions, and we invite you to call (617) 975-9770. You can also find more information on our website at www.bidmc.org/cardiacrisk and on the CDC and FDA websites:

CDC: <https://www.cdc.gov/HAI/outbreaks/heater-cooler.html>

FDA:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm20082725.htm>

Sincerely,

A handwritten signature in black ink that reads "Patricia H Folcarelli". The signature is written in a cursive style with a large initial "P".

Patricia Folcarelli, RN, PhD
Interim Senior Vice President, Health Care Quality

A handwritten signature in black ink that reads "Sharon B. Wright". The signature is written in a cursive style with a large initial "S".

Sharon B. Wright MD, MPH
Director, Infection Control/Hospital Epidemiology