

November 7, 2016

We are contacting you today out of an abundance of caution as you have been identified in our clinical records as a cardiac surgery patient who might be impacted by recent notifications issued by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

The CDC and FDA recently notified health care providers across the U.S. that certain units of a device used during your open-heart procedure, the LivaNova PLC Stöckert 3T heater-cooler, have been linked to cases of a rare bacterial infection caused by *Mycobacterium chimaera*, a species of bacteria known as nontuberculous mycobacterium or “NTM.” While investigations by the CDC and FDA are ongoing, new information indicates that some of these heater-cooler devices were contaminated during the manufacturing process. The notices and warnings issued by the CDC and FDA are widespread across the U.S. because more than 60% of surgeries using a heater-cooler device are performed using the Stöckert 3T device (this number is even higher in pediatric populations). In an effort to spread awareness of the investigational findings and to share additional information and resources with you, the CDC and FDA have asked us to provide you with the following information:

For patients who have had open-heart surgery during which a Stöckert 3T heater-cooler device was used, the chance of getting an NTM infection is very low; in hospitals where at least one (1) infection has been identified, the CDC estimates the risk of infection to be between 1 in 100 and 1 in 1000. As of the date of this letter, Arnold Palmer Hospital for Children has not had any reported cases of NTM infection among its open-heart surgery patients.

The infection associated with this device is slow to advance and can be difficult to diagnose. Symptoms can develop years after surgery, so it is important for you to be aware of these symptoms:

- night sweats
- muscle aches
- weight loss
- fatigue (low energy, feeling weak or tired over time)
- unexplained fever

This infection cannot be spread person-to-person.

As your healthcare provider, we want to keep you informed and be available to answer any questions that you or your family may have. We have established a number for you to call if you have additional questions. When calling, be prepared to leave your contact information so that we may review your medical record and call you back. The number to call is 321-843-7200. If you prefer, you may also contact your primary care physician, cardiologist or cardiac surgeon.

You may also reference the web links below for additional information:

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

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm>

<http://www.arnoldpalmerhospital.com/pediatric-specialties/pediatric-cardiology-and-cardiac-surgery>

Sincerely,

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