



Penn Presbyterian Medical Center

September 19, 2016

Dear Patient

Our records reflect that you underwent a specific type of heart surgery at Penn Presbyterian Medical Center between October 1, 2013 and December 17, 2015. The purpose of our letter is to inform you about a device-related issue that is affecting many hospitals in this country and in Europe.

The U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have notified hospitals about the risk of infection that has been linked to certain heater-cooler devices used in conjunction with the cardiopulmonary bypass machines during cardiac surgeries. The infection that has been associated with these devices is known as non-tuberculous mycobacterium or NTM. The bacteria involved commonly are found in water and soil. In most cases, this infection can be treated with antibiotics.

Recently, we became aware that four of our patients who had cardiac surgeries performed during the time period identified above have been diagnosed with a NTM infection. Based on our experience, with less than one percent of our patients undergoing cardiac surgery involving the use of cardiopulmonary bypass having been diagnosed with this infection, and our review of reports from other centers, we believe it is very unlikely that you have or will develop an infection. We nonetheless felt it was important to notify you about this issue and provide you with additional information.

NTM is a slow-growing bacterium. It therefore can take from several months to several years for symptoms to develop. If you have any symptoms such as fever lasting more than a week; pain, redness, heat or pus from your cardiac surgical incision, night sweats, or weight loss not explained by any other illness, you should contact your physician to be evaluated.

Consistent with our commitment to patient safety, we always have adhered to manufacturer guidelines for disinfecting and maintaining these heater-cooler devices. After the CDC issued its advisory with recommendations for more stringent disinfection practices, we immediately implemented those recommendations and went beyond what the CDC recommended. Although these infections are rare, we replaced all of our heater-cooler devices from the manufacturer that was the focus of the FDA's investigation with heater-cooler devices from another manufacturer to address this potential risk.

We have set up a toll-free number: 1-800-890-6963 and would be pleased to answer any questions and, if indicated based on the results of a brief screening survey, arrange an appointment with one of our providers. If an appointment is scheduled, it will be at no cost to you. Additional information also is available via our website: <https://www.pennmedicine.org/ppmc-cardiac-bypass>

The health and safety of our patients is our paramount concern and we remain committed to ensuring your health and well-being.

Sincerely,

Michele M. Volpe
Chief Executive Officer

Kevin M. Fosnocht, M.D.
Chief Medical Officer