



INSTITUT UNIVERSITAIRE
DE CARDIOLOGIE
ET DE PNEUMOLOGIE
DE QUÉBEC

AFFILIÉ À  UNIVERSITÉ
LAVAL

Quebec City, October 28, 2016

Re: Patients who have undergone open-heart surgery at the Quebec Heart and Lung Institute [Institut universitaire de cardiologie et de pneumologie de Québec – Université Laval], between November 1, 2011, and October 28, 2016

The Institut universitaire de cardiologie et de pneumologie de Québec – Université Laval (the Institute) and many hospitals across North America have been informed of a low risk of infection due to bacteria present in certain devices (heater-cooler systems) used during open-heart surgeries performed between November 1, 2011, and October 28, 2016. The Institute ensures the implementation of best practices for preventing and controlling infections and, to our knowledge, none of our 9,500 patients who have undergone open-heart surgery since November 2011 have been infected with this bacteria.

Our records indicate that you underwent surgery within the period during which this device was used. Although the risk of infection is minimal, we feel the need to inform you of this possibility.

The heater-cooler systems in question were contaminated by the *Mycobacterium chimaera* bacterium during their manufacturing in Germany. This type of bacterium is commonly found in nature and rarely causes disease in healthy people. However, patients who have been exposed during open-heart surgery may develop symptoms up to five years after surgery.

The *Centre d'expertise en retraitement des dispositifs médicaux* (CERDM – the Centre of Expertise for Medical Devices Reprocessing) of the *Institut national de santé publique* (the National Institute of Public Health) and the *ministère de la Santé et des Services sociaux* (Ministry of Health) have been notified of the issue.

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While the infection with *Mycobacterium chimaera* is not contagious, it could be serious and must be diagnosed by laboratory testing (microbiology) when symptoms occur. Treatment involves taking antibiotics.

We recommend that you consult a health care professional if you experience the following symptoms **for more than one week**:

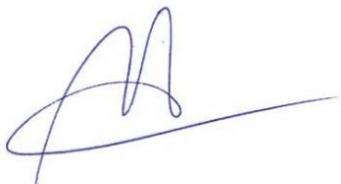
- fever;
- unexplained weight loss;
- muscle and joint pain, night sweats, and fatigue.

If this occurs, we suggest you give a copy of this letter to the health care professional during your appointment.

If you have any questions or concerns regarding your health, you can call Info-Santé by dialling 8-1-1. You can also contact us if you have further questions. The number for the dedicated call centre at the Institute is **418-656-8711, ext. 8010**.

The Institute takes the well-being and safety of its patients very seriously. We wanted to get in touch with you for the sole purpose of monitoring your medical condition as adequately as possible. **Note that preventive screening in the absence of symptoms is not useful since the bacteria cannot be detected.**

Please be assured that we understand the concerns that this news can cause, and the Institute is entirely at your disposal to provide you with all the support and care you may need.

A handwritten signature in blue ink, appearing to be 'FA', with a long horizontal line extending to the right.

Dr. François Aumond
Director of Professional Services