



January 20, 2017

Dear Nemours Patient, Parent or Guardian,

We are contacting you because there has been a national recall of a medical device that was used during your child's cardiac surgery. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) has reported that the medical device (Stockert 3T), used with both adults and children to heat and cool the blood during cardiac surgery, has been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a type of bacteria known as nontuberculous mycobacterium (NTM). For patients who had surgery during which the device was used, the chances of acquiring the NTM infection are very low. The CDC estimates the risk to be less than 1 percent. It is also important to note that because the NTM infection is slow-growing, it is difficult to diagnose, and it is possible to develop symptoms years after surgery. The infection is not contagious and cannot be spread person-to-person.

We want you to be aware of the recall, to provide you with more information and help to alleviate concerns about any potential impact on you or your child, and to share what steps we have taken to ensure the health of our patients.

Upon learning of the potential for contamination via 3T heater-coolers from reports released by European health authorities, the Nemours Cardiac Center elected to immediately remove the 3T device from service, replacing the device with a heater cooler from a different vendor. This action predates heater-cooler announcements issued by the CDC by nearly an entire year.

In addition, since learning of the recall we reviewed the medical records of every patient who underwent a cardiac procedure that involved the use of the Stockert 3T device, including a review of the laboratory data for any evidence of this infection in our patients. We found no evidence of the NTM infection in this review and to date, we have not observed any cases of the NTM organism associated with the Stockert 3T device in our patients.

In following CDC recommendations, we ask that you contact your primary care physician or your cardiologist if you or your child has had any of the following symptoms since the surgery:

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

You may also contact CDC Info with any questions you may have at 800-CDC-INFO (800-232-4636) or <https://www.cdc.gov/dcs/ContactUs/Form>.

Thank you for placing your trust in Nemours/Alfred I. duPont Hospital for Children (N/AIDHC) and affording us the privilege of caring for your child. We value your trust immensely and are dedicated to providing your child the highest level of quality, safety, clinical expertise and patient care possible.

Sincerely,

Stephen T. Lawless, MD, MBA  
Senior Vice President

Christian Pizarro, MD  
Chief, Division of Pediatric Cardiothoracic Surgery

Nemours Children's Health System

Nemours/Alfred I. duPont  
Hospital for Children

Nemours BrightStart!

Nemours CareConnect

Nemours Center for  
Children's Health Media

Nemours Children's Clinic

Nemours Children's Hospital

Nemours Children's Primary Care

Nemours Children's Specialty Care

Nemours Children's Urgent Care

Nemours duPont Pediatrics

Nemours Estate

Nemours Fund for  
Children's Health

Nemours Health &  
Prevention Services

Nemours Office of Policy  
and Prevention

Nemours SeniorCare