# El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

| | |
|---|---|
| **NOMBRE DEL DISPOSITIVO MÉDICO** | Intercambiador de Calor |
| **NO. IDENTIFICACIÓN RISARH** | I1408-333 |
| **REFERENCIAS DEL DISPOSITIVO MEDICO** | 1T Y 3T |
| **REGISTRO SANITARIO** | 2009EBC-0003841 |
| **INDICACIONES Y USO ESTABLECIDOS** | Es un equipo portátil de refrigeración y calentamiento de 2 o 3 circuitos (independientes de las conexiones de agua) indicado para ser utilizado con una máquina de corazón-pulmón o para controlar la temperatura de los circuitos de agua durante una perfusión extracorpórea. incluye circuitos de agua para control de la temperatura de la sangre (en el oxigenador), en las mantas térmicas o hipotérmicas o en las soluciones de cardioplejia |
| **NOMBRE DEL FABRICANTE** | Sorin Group Deutschland |
| **DESCRIPCION DEL PROBLEMA** | El fabricante informa que potencialmente se puede presentar contaminación y multiplicación por Mycobacterium quimera al interior del equipo si las instrucciones de desinfección no se siguen, además de la contaminación con chimaera Mycobacterium, dichas micro bacterias pueden estar presentes en el agua de la llave, esta práctica puede conllevar a que se presenten potencialmente eventos adversos serios sobre el paciente |
| **FUENTE** | ANEXO 1 |
| **FECHA DE NOTIFICACION** | 08 de Agosto de 2014 |

**RECOMENDACIÓN:**

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos. Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

**ANEXO 1**

## A22770 - High Priority Medical Device Alert

**Medical Device Ongoing Action**
**Updated:** August 6, 2014
**UMDNS Terms:**
- Warming/Cooling Units, Patient, Circulating-Liquid [12074]

**Suggested Distribution:**
- Clinical/Biomedical Engineering
- Cardiology/Cardiac Catheterization Laboratory
- Perfusion
- Nursing
- OR/Surgery
- Infection Control

**Geographic Regions:**
- Worldwide

### Sorin—Heater Cooler Devices: May Become Contaminated

**Product Identifier:**
Heater Cooler Devices: (1) Model 1T (discontinued), (2) Model 3T *[Capital Equipment]*
**Manufacturer:**
- Sorin Group Deutschland GmbHLindberghstrasse 25, D-80939 Muenchen, Germany

**Problem:** In a July 14, 2014, Important Information letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), and in a July 28, 2014, Important Information letter submitted by ECRI Institute member hospitals, Sorin states that a slow-growing *Mycobacterium chimaera* may multiply in the above systems if disinfection instructions are not followed, potentially forming a biofilm. The firm also states that some cardiac surgey patients have been infected with a *Mycobacterium chimaera*. Current practices for monitoring the contamination of a cardiac surgery theater may not identify the slow-growing, chemically resistant organisms involved. *Mycobacteria* organisms can also be found in water, including tap water sources. For additional information on *Mycobacteria*, refer to Attachment 1 of the Important Information letter. Sorin states that water in the heater cooler devices is not intended to directly contact the patient. It further states that one of the highest risks of contamination for the patient is a direct contact transfer of water/solution droplets containing *Mycobacteria* into the surgical field. Air distribution within the cardiac surgery theater, including air conditioning, ventilation units, and heater cooler device fans, may also be a transmission method for *Mycobacteria*.
**Action Needed:**
Identify any affected product in your inventory. If you have any affected product, verify that you have received the Important Information letters, Attachment 1, Attachment 2, and Customer Response Form from Sorin. Complete the Customer Response Form, and return it to Sorin, following the instructions on the form. Sorin states that you may continue to safely use the above heater cooler devices following the instructions in the Operator's Manual. The firm recommends that you perform the following actions:

- Review the materials from Sorin regarding proper water management for your cardiac surgery theater. Ensure that relevant personnel understand *Mycobacteria* and the potential contamination risks for cardiac surgeries. Review the introductory information in Attachment 1.
- Review your heater cooler operating practices and cardiac surgery theater water management practices. Also evaluate affected product for potential contamination.
- Refer to the heater cooler device operator's manual and/or Attachment 2 and review the necessary disinfection practices to ensure your practices are aligned with the directions.
- If you are concerned that your facility's compliance with operating instructions may be in question, perform microbiological sampling of the water in your heater cooler device, disinfect the device, and determine if decontamination is necessary.

Forward a copy of the Important Information letter to any relevant personnel. If you have further distributed affected product to another facility, notify your Sorin local representative of the transfer, and forward a copy of the Important Information letter to that facility.

**For Further Information:**
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E-mail: paul.williams@sorin.com
Europe
Christian Peis, Sorin director of quality assurance
Tel.: 49 (89) 32301152
E-mail: SGD@fsca@sorin.com
Website: Click here

**References:**

- Germany. Federal Institute for Drugs and Medical Devices. Urgent safety notice for Sorin heater cooler devices, Sorin Group Deutschland GmbH [online]. 2014 Jul 22 [cited 2014 Aug 4]. Available from Internet: Click here.

**Comment:**

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

**Source(s):**

- 2014 Aug 4. BfArM (Germany). 4000/14
- 2014 Aug 4. BfArM (Germany).
- Reference No. IIS 9611109-07-14-14 (includes reply form)
- 2014 Aug 4. Member Hospital.
- Sorin letter submitted by ECRI Institute member hospital; Reference no. IIS 9611109-07-14-14 (includes reply form)
- 2014 Aug 6. Manufacturer. Manufacturer confirmed information contained in source material