

## LivaNova 3T Heater-Cooler Deep-Cleaning Service - FAQs

April 2018 – Valid only for 3T Heater-Cooler users in the US

### Q1: What is the Deep-Cleaning Service?

**A1:** The deep-cleaning service is a free of charge special service implemented by LivaNova that allows facilities to return heater-cooler units for a full cleaning, disinfection and replacement of connectors and tubing. The deep-cleaning service is currently implemented at LivaNova facilities in Munich. LivaNova recently received FDA agreement to allow us to offer a secondary deep-cleaning center in the US that will support US heater-cooler units.

### Q2: How long does it take for a Deep-Cleaning Service?

**A2:** The complete deep-cleaning process requires a minimum of four weeks between the date the unit is returned to LivaNova and the date the unit is returned to the hospital.

### Q3: Will I be able to use a loaner device while my 3T(s) is undergoing the deep-cleaning service?

**A3:** After LivaNova receives your request form, someone will contact you to discuss logistics. At that time, you will have the opportunity to discuss whether or not you will need a loaner unit while your device(s) is undergoing the deep-cleaning service.

### Q4: In cases where additional units are confirmed or suspected of being contaminated with M. chimaera at the same facility, will LivaNova provide multiple loaners?

**A4:** To ensure we can maximize the number of hospitals we can serve at the same time, we will allocate a maximum of one loaner device per institution. In case an institution has more than one device contaminated or suspected to be contaminated with M. chimaera, a rotation mechanism should be implemented. Once the first device is returned to the hospital after deep cleaning, a second device can be shipped to LivaNova for deep cleaning. When all devices have completed deep cleaning and the last device is returned to the hospital, the loaner will have to immediately be returned to LivaNova.

### Q5: How can I submit to LivaNova a request for Deep-Cleaning and for a loaner?

**A5:** You may submit your deep-cleaning request by completing a Deep-Cleaning Service Request Form which is available for download at [www.livanova.sorin.com/3T](http://www.livanova.sorin.com/3T). Once you've completed the form, please email it to [3T.US@LivaNova.com](mailto:3T.US@LivaNova.com).

### Q6: What are the limitations for devices suitable for Deep-Cleaning Service?

**A6:** Heater-coolers produced before 2009 will not be eligible for the deep-cleaning service.

**Q7: Why does LivaNova not provide Deep-Cleaning Service on devices produced before 2009?**

**A7:**

- a. The typical average expected useful lifetime of medical devices is ~10 years
- b. Overall condition of older devices generally requires additional repair work which is not included in the deep-cleaning service and would be subject to additional charges
- c. Design changes during the product lifecycle

**Q8: How do I know when my 3T Heater-Coolers were manufactured?**

**A8:** All 3T Heater-Coolers have a label affixed to the back panel of the device showing the serial number (beginning with 16S-) and date of manufacture.