IMPORTANT SAFETY COMMUNICATION

October 23, 2015

Dear Hemotherm® Dual Reservoir Cooler-Heater and ECMO Heater® Customer,

Last week FDA issued a Medical Device Safety Communication regarding Nontuberculous Mycobacterium (NTM) Infections Associated with Heater-Cooler Devices *to heighten awareness about infections associated with heater-cooler devices and steps health care providers and health facilities can take to mitigate risks to patients.* For more information, see FDA's Safety Communication available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm.

Gentherm would like to inform you that we have had no reported incidents associated with NTM contamination or infection involving Gentherm's cooler-heater devices. However, there is one known reported bacterial contamination related to Cupriavidus Pauculus/R. Paucula, which is widely found in hospitals, associated with an ECMO Heater®. An investigation of this 2009 incident determined it may have resulted from a failure to follow the device's cleaning procedures. It is incumbent on all hospitals and clinics to develop and maintain an adequate infection control plan at all levels to produce the greatest level of patient safety from nosocomial infections.

Gentherm recommends following the proper cleaning procedures identified in the cleaning section of the appropriate Operation & Technical Manual. Below summarizes important steps from Gentherm's cleaning procedures as well as those recommended by FDA. Be sure to read and understand all of the information in the appropriate Operation & Technical Manual as the below summary is not a substitution for the complete procedure.

- **Please follow Gentherm's cleaning procedure and preventative maintenance schedule** in the Operation & Technical Manual to minimize the risk of bacterial growth and subsequent patient infection.
- Use only distilled water. Do not use tap water to rinse, fill, refill or top-off water tanks. Although FDA suggests using sterile water or water that has been passed through a filter of less than or equal to 0.22 microns, there has been no objection to using distilled water.
    - Note: Deionized water and sterile water created through reverse osmosis is not recommended because it may promote corrosion of the metal components of the system.
- FDA suggests directing the cooler-heater's vent exhaust away from the surgical field to mitigate the risk of aerosolizing cooler-heater tank water into the sterile field and exposing the patient. Please note, the exhaust vent on the

Hemotherm® device is on the bottom of the unit and is not directed towards the surgical site.

- FDA suggests immediately removing from service cooler-heater devices that show discoloration or cloudiness in the fluid lines/circuits, which may indicate bacterial growth.
    - Additionally, Gentherm recommends replacing all external water lines and hoses that show discoloration or cloudiness.
- Contact Gentherm if you have any questions or suspect the cooler-heater device has led to patient infections.

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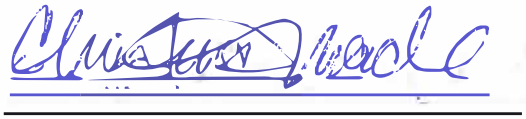
Gentherm is proactively communicating with FDA and national health agencies to better understand the risk and to develop further strategies to minimize patient exposure. Any additional information will be communicated as it becomes available. Thank you for your cooperation in this important matter.
Sincerely,



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