URGENT Medical Device Recall

7/18/2019

Dear Valued Customer,

This is to inform you that Gentherm Medical, LLC (formerly Cincinnati Sub-Zero) is conducting a voluntary product recall involving:

Blanketrol II Hyper-Hypothermia System, Models 222R and 222S
Affected Serial Numbers are: Model 222R (071-18490 – 123-20534)
Model 222S (104-2-00001 – 161-2-01848)

See enclosed product labels in Appendix A for ease in identifying the product at the user level.

The purpose of this letter is to advise you that warnings have been clarified stating that exceeding 40°C for extended periods may cause tissue damage. See Appendix B for specific changes that have been made to the device manuals.

Immediately examine your inventory and update manual(s) subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall letter.

INSTRUCTIONS TO CUSTOMERS:

1) Access updated manuals and ensure that obsolete manuals are removed from service. Updated manuals may be accessed via www.gentherm.com or physical copies may be requested from Gentherm Medical, LLC at 1-888-437-5608.
2) Ensure that all users are informed of the contents of this letter. If you have further distributed this product, please provide those accounts with a copy of this notice.
3) Please **complete and return the enclosed response form** as soon as possible to acknowledge receipt of this notification and to inform Gentherm Medical, LLC that you have performed and completed the requested actions. Return the form by e-mail to FA2019-004/010@gentherm.com, or mail to:

   Gentherm Medical, LLC
   12011 Mosteller Road
   Cincinnati, OH 45241

This recall should be carried out to the user level. Your assistance is appreciated and necessary to prevent tissue damage. If you have any questions, call Gentherm Medical Technical Support at 1-888-437-5608.

This recall is being made with the knowledge of the Food and Drug Administration.

Sincerely,

Stephanie Vocke
Quality & Regulatory Engineer

Appendix A: Blanketrol II Product Labels

Appendix B: Blanketrol II Hyper-Hypothermia System Manual Updates

Affected Manual	Updates
Changes are designated in RED **See updated manual(s) for more details.**	
56230 (222R Operation and Technical Manual): **WARNINGS section** **57126** (222R Operation Manual): **WARNINGS section**	WARNING: A physician's order is required for setting blanket temperature and use of equipment. At least every 20 minutes, or as directed by physician, check patient's temperature and skin condition of areas in contact with blanket; also, check blanket water temperature. Pediatric, temperature-sensitive, patients with vascular disease and operating room patients are at greater risk for developing tissue injuries, and this should be considered when selecting the temperature, duration of therapy and frequency of skin checks. Notify the physician promptly of any change in patient status in order to avoid serious injury or death. WARNING: The method of temperature control provided by all hyper-hypothermia units presents the danger of heating or cooling body tissues, particularly the skin, to a point where they are injured, i.e., burns or frostbite, respectively. The clinician is responsible for determining the appropriateness of the temperature limits in dependency to time. Exceeding 40°C water temperature for extended periods can cause tissue damage and burns. Clinical judgment should be used to determine the safe maximum contact periods based on patient age, clinical condition and current medications. Depending on the extent and severity of a burn, very serious and even fatal complications may arise.
57947 (222S Operation and Technical Manual): **WARNINGS section, Sections 2-4, 3-2, 3-3, and 3-4** **56277** (222S Operation Manual): **WARNINGS section, Sections 3-2, 3-3 and 3-4**	WARNING: A physician's order is required for setting blanket temperature and use of equipment. At least every 20 minutes, or as directed by the physician, check patient's temperature and skin integrity of areas in contact with blanket; also, check the BLANKETROL II's water temperature. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients, diabetics and patients with Raynaud's Disease are at greater risk for developing tissue injuries, and this should be considered when selecting the temperature, duration of therapy and frequency of skin checks. Notify the physician promptly of any change in patient status in order to avoid serious injury or death.
57947 (222S Operation and Technical Manual): **WARNINGS section and Section 2-4** **56277** (222S Operation Manual): **WARNINGS section**	WARNING: The method of temperature control provided by all hyper-hypothermia units presents the danger of heating or cooling body tissues, particularly the skin, to a point where they are injured, i.e. burns or frostbite, respectively. The clinician is responsible for determining the appropriateness of the temperature limits in dependency to time. Exceeding 40°C water temperature for extended periods can cause tissue damage and burns. Clinical judgment should be used to determine the safe maximum contact periods based on patient age, clinical condition, and current medications. Depending on the extent and severity of a burn, very serious and even fatal complications may arise.

Recall Response Form

Please complete this form after the instructions provided in the recall letter. Return the completed form by mail to Gentherm Medical, LLC, 12011 Mosteller Road, Cincinnati, OH 45241, by fax to (513)772-9119 or scan and e-mail to FA2019-004/010@gentherm.com.

Please check ALL appropriate boxes.

☐ I have read and understand the field notification instructions.

☐ I have ensured that all users are informed of the contents of this letter.

☐ Indicate disposition of recalled product:

☐ Corrected: _____
(Specify serial number(s) and date)

☐ Returned: _____
(Specify serial number(s), and date)

☐ Destroyed: _____
(Specify serial number(s), and date)

☐ I have identified and notified my customers that were shipped or may have been shipped this product by;

(Specify date and method of notification)

OR

☐ Attached is a list of customers who received/may have received this product. I would like Gentherm Medical to notify my customers.

Signature	Date
Printed Name	Email Address
Facility Name	Facility Address, City, State, Zip Code
Phone Number	