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Cincinnati Sub-Zero

16 February 2010

Urgent Field Safety Notice

PRODUCT: Cardiac Blankets for use with Warm Air Thermal Regulating Units labeled "Sterile"

The following lot number produced between
November 1, 2007 and November 12, 2009

Recalled FilteredFlo Cardiac Blanket Cat. No. 542	
Lot numbers affected:	07279

Type of Action: Negligible likelihood of occurrence of death or serious deterioration in state of health

NOTE: This Field Safety Notice (FSN) is related to the FSN dated 19 November 2009, which was issued by Cincinnati Sub-Zero Products, Inc. An additional FSN is being issued because lot number 07279 has now been added to the list of affected Cardiac Blanket lot/batch numbers. If you are receiving this notice for the first time, our records indicated that the lot numbers mentioned in the first FSN, lot numbers 07424 and 08813, were never distributed to you. Please read the following notice and respond back as soon as possible.

REASON FOR FIELD SAFETY NOTICE

This recall has been initiated because Cincinnati Sub-Zero Products, Inc. (CSZ) has discovered inconsistent seals on some of the bags in which the Cardiac Blankets are packaged. An inconsistent seal means that, although the product was sterilized, the sterile state of the device may not have been maintained. There have been no reports of infections from use of the Cardiac Blankets and no one has been injured from the use of the Cardiac Blankets.

The device does not contact the wound site directly. The wound is protected from contamination by a sterile dressing. In addition, the act of wrapping the Curlex around the appendage to hold the sterile Telfa pad in place results in the care giver touching the non-sterile parts of the appendage so sterility is compromised prior to applying the Cardiac Blanket. If the device did become contaminated due to a faulty seal, there would be a low probability of harm of infection resulting from the use of the non-sterile Cardiac Blanket because there is no contact between the pad and the wound.: The method in which the Cardiac Blanket is used provides risk mitigation since there are sterile barriers between the Cardiac Blanket and the wound site.

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ROOT CAUSE WITH CORRECTIVE ACTION

We have traced the root cause of the poor seals to the seal arm on the equipment that seals the bag. The seals produced by this machine passed visual inspection tests but some of the product tested failed the dye testing due to microscopic holes in the seal. All Cardiac Blankets should be returned. A new sealing machine has been delivered and is being validated for use.

INSTRUCTIONS TO USER CUSTOMERS:

Assume your Cardiac Blanket(s) are NOT Sterile: Do not use the Cardiac Blankets directly on the wound site. Cardiac Blankets should be returned CSZ distributor representatives, Healthlink.

Obtain Return Authorization from CSZ to return your Cardiac Blankets: Call Healthlink at +31-(0)13-5479300 for a Return Authorization and specific instructions on packaging and returning the devices.

Complete the RETURN RESPONSE form to acknowledge receipt of this notification and to identify quantities being returned for credit. Return the form by mail to Healthlink Europe BV, Centaurusweg 123, 5015 TC TILBURG, The Netherlands or scan and e-mail the information to apo@healthlinkeurope.com

Authorized European Representative for Cincinnati Sub-Zero

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