

Press Release

No. 43us / July 20, 2009

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Dräger Initiates a Voluntary Device Recall of Stabilet Contacts Current Users

Telford, PA – Draeger Medical Inc. recommends the removal of Stabilet Infant Warmer models 200, 300, 1250, 1500, 200/3000, 2000, 2200/3200, 3000, and 3200 from service and replacing them with alternative warmers as soon as it is feasible.

This action is in response to an event that took place in a neonatal unit of a hospital in Minnesota in 2008. ECRI conducted an investigation of the event and concluded that the likely cause was the Stabilet. Dräger has not been given the opportunity to investigate this incident or to test the Stabilet at issue, and therefore; we cannot comment on ECRI's investigative conclusions. However, Dräger determined to err on the side of caution and has initiated a voluntary recall. As part of this recall, Dräger agrees with ECRI's recommendation to remove the Stabilets from service as soon as it is feasible. The recall recommends that the hospital take the following actions:

- (1) Hospitals should immediately begin planning to remove the referenced models from service:
 - a. Hospitals with sufficient number of unaffected models to meet anticipated clinical needs should immediately remove the referenced warmers from service.
 - b. Hospitals currently unable to provide required heating therapy if these units are removed from service should
 - i. Begin budgeting for the replacement of the units; and
 - ii. Limit use of the referenced models to patients NOT requiring O₂ – enrichment may increase the risk of fire. Hospitals should inform all potential users of this restriction and clearly mark referenced units to reinforce this message.
 - iii. Use a different heating modality (e.g., an infant incubator) if an infant requires O₂ therapy (whether supplemental or via intubation) and no unaffected warmers are available.
- (2) Once removed from service, the warmers should be rendered unusable by removing the heating element and the power cord. These warmers should not be used or sold for any other purpose.

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In 2004, Dräger acquired from Hill-Rom Co., Inc. (the manufacturer of this product) the Stabilet product line of radiant infant warmers. Hill-Rom discontinued manufacturing the Stabilet product line in 1998, six years prior to its sale to Dräger. Service support and spare parts for Stabilets were discontinued at the end of 2003. All known users of this product line were informed that this product was discontinued at this time.

If you need further information please contact Mike Kelhart (1-800-543-5047 ext 2349). A recall notification is being sent out to all known current users and is available in the Dräger website at www.draeger.com/Stabilet.

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The Drägerwerk AG & Co. KGaA is an international leader in the fields of medical and safety technology. Dräger products protect, support and save lives. Founded in 1889, in 2008 Dräger generated revenues of around EUR 1.9 billion. The Dräger Group is currently present in more than 190 countries and has about 11,000 employees worldwide. Please visit www.draeger.com for more information.

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