URGENT FIELD SAFETY NOTICE

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

March 28, 2012 GEHC Ref#35012

To: Materials Manager / Central Supply Coordinator
Chief of Anesthesia
Risk Manager

RE: **Vital Signs enFlow IV Fluid Warmer Strap: Product Number 980304 and 980304EU**

GE Healthcare has recently become aware of a potential safety issue. The EnFlow Warmer Strap does not meet the requirements of the biocompatibility standard (ISO 10993) for products that may have contact with skin for less than 24 hours.

In addition, the strap is produced from natural rubber, and it has been found to have trace amounts of latex. When tested for proteins that can produce an allergic reaction, however, the results were "too low to detect".

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

Based on the results of biocompatibility tests, acute tissue injury due to toxic material exposure may occur. The tissue injury is localized and not life-threatening and would normally be expected to heal with standard medical treatment and under medical supervision.

Even though there is a potential safety issue with the enFlow Warmer strap as a result of failing the biocompatibility standards; GE Healthcare has not received any reports of any injuries to date.

Affected Product Details

All enFlow Warmer Straps in the field present a potential for tissue injury.
Sold separately as Product #: **980304 and 980304EU**
Included as an accessory in following enFlow products:

980100
980100EU
980105VS

Safety Instructions

1. Discontinue use of the enFlow IV Fluid Warmer Strap until a replacement is issued.
2. Please isolate and discard all affected products.
3. Discontinue further distribution.
4. If you have forwarded this product to any other healthcare institutions, please forward a copy of this letter to those institutions.
5. Return the attached response form even if no recalled product is in inventory. When there is no product to be replaced, circle no affected product. This step is required for VSD to confirm communications with all customers.
6. Please fill out the attached Confirmation form and fax back per its instructions to obtain replacement product.

Product Correction

Vital Signs will send all affected customers a replacement strap when available.

Contact Information

If you have any questions or concerns regarding this notification, please contact Customer Service.

This information has been communicated to the appropriate National Competent Authorities.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Thank you,

[redacted]

[redacted]
Vice President QARA
GE Healthcare Systems

[redacted]

[redacted]
Chief Medical Officer
GE Healthcare

URGENT FIELD SAFETY NOTICE CONFIRMATION

RE: MEDICAL DEVICE CORRECTION

ATTN: Customer Service (email VitalSignsCustomerService@ge.com)

It is important that we confirm our customers have received this correction notice. As such, we require that you complete this confirmation form and fax it back to VSD.

FAX NUMBER: +1 800-535-7923

This step needs to be completed before the replacement and shipping process can commence. Please expect a 7-8 week timeframe for receiving replacement product. Any questions, please call Customer Service.

Name of Account: _____Account #_____

Contact Name: _____ Department: _____

Telephone Number: _____ Email: _____

Address #1: _____

Address # (room, etc.): _____

City: _____State: _____ Zip Code_____

Print Name:
_____

Signature: _____Title: _____ Date: _____

Do you have any affected product? **Yes/No**

How many affected products do you have? _____

Do you require a no charge PO for the replacement order, if so, please provide now: N/C PO #_____

Customer Support will contact you with the return details (if required) and the replacement order information.