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RI 9287 8916 3GB
30th of January 2007

Dear valued customer,

Re: Product Recall of Sterile Securement Device Products

Drain-fix 680M and 685M
Epi-fix 670M
Epi-fix Window 675M
CentralGard 667M and 668M

Unomedical recently discovered a fault in our packaging machine causing a possible defect peel pouch in one out of six peel pouches. We haven't experienced an increased number of complaints due to this, but, since this may question the integrity of our products we have decided to initiate a recall. We fully appreciate the seriousness of such an occurrence, and have taken appropriate actions, and continue to monitor our processes.

Having completed investigations, we are now initiating a recall of codes and lots for products that might be affected.

The packaging process of our sterile securement devices has, after our completed investigation been changed and improved to prevent a failure re-occurrence. The improvements were:

1. Manufacturing parameters have been optimized.
2. Additional quality assurance measures have been implemented.

Our records show you have taken delivery of this product range as per attached "Recall Questionnaire". Please follow the steps below:

1. Please examine the enclosed questionnaire and immediately put all products you may have on hold
2. Please forward "Recall Questionnaire for end users" to your customers, asking them to return the affected products to you.
3. Please return the "Recall Questionnaire for distributors" and "Recall Questionnaire for end users" to Unomedical as soon as possible

We are requesting you to return all identified product batches to the below mentioned address as soon as possible, so we can remove defect products, and ensure full product replacement for you and your customers as soon as possible.

Unomedical Ltd.
Unit 3
Stroudwater Business Park
Brunel Way
Stonehouse
Glos. GL10 3SX
United Kingdom

Please mark all returned products clearly with "Recalled products" or similar.

Where you are holding inventories
Please complete the attached "Recall Questionnaire" and fax/ e-mail it to our Customer Service department (fax: [redacted] or e-mail: [redacted]@unomedical.com) for the quantity of products you have in stock. We will contact you separately on the issue of replacement supplies. Please forward us a copy of the completed "Recall Questionnaire for Distributors" with information related to the products you have sold to your customers.

Where you have products sold to customers
Please send a copy of this letter to the customers to whom you have sold these products and ask them to account for products held in stock or sold to their customers. Please ask them to stop using the product immediately and request them to return the stock to you.

If applicable, please ensure that your customers provide a copy of this letter, and of the enclosed not yet filled in "Recall Questionnaire for End Users" for completion by those to whom your customers have supplied products.

On behalf of the company, please accept our apologies for the inconvenience caused.

Sincerely yours,
UNOMEDICAL LTD

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Manufacturing Unit Manager