

Penn Works Owlerton Green Sheffield S6 2BJ

Telephone: (0114) 234 4231

Fax: (0114) 231 4966

Email: info@swann-morton.com Web: www.swann-morton.com

Helle Egebjerg Kure
Sales Director Nordic Region
Unomedical a/s a ConvaTec Company
Birkerod Kongevej 2
DK 3460 Birkerod
Denmark

3rd September 2012

Urgent FIELD SAFETY NOTICE

Recall of Swann-Morton Sterile Carbon Steel Stitch Cutter,

REF 0420, LOT No. 8641108

Dear Helle,

Swann-Morton Ltd is initiating a Recall of one Batch/LOT of its Sterile Stitch Cutter Blades, Ref No. 0420 from Lot 8641108.

We have determined that there is a possibility that the stitch cutter could be broken within the sealed unit pack.

If a broken stitch cutter is discovered it cannot be used and may delay the removal of sutures from a patient causing anxiety.

Our records indicate that your facility has received 71 boxes of the concerned product from LOT 8641108.

Please note that only the product listed is affected. No other Swann-Morton product is involved by this Field Safety Notice.

INSTRUCTIONS

- Please immediately discontinue use of this product and remove all of the affected units from your inventory. Segregate the product in a secure place pending return to Swann-Morton Ltd.
- 2 Please complete the attached verification form (even if you do not have any product to return).
- 3 When completed, please fax the verification form immediately to Swann-Morton Ltd, +44 (0) 114 2314966 for the attention of Customer Services.

Arrangements for return and replacement of products will be made with you as soon as possible.

4 Please pass this notice to any organization where the potentially affected devices have been transferred. (If Applicable.)

The UK Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Yours sincerely

J. S Hawkins

QA/RA Systems Manager