URGENT FIELD SAFETY NOTICE:
INSTRUCTIONS TO END USER

Commercial Name: Unomedical Sterile Urine Drainage Bags
LOT No: Please see attached sheet for reference numbers & affected LOT numbers
FSCA Id: 2010/11 URI
Type of action: Return of product to supplier

26th November 2010

Description of the problem:
Unomedical would like to inform you of a potential manufacturing irregularity during the production of certain units of Unomedical urine drainage bags (sterile leg bags (350, 500 and 750ml), sterile 2l night bags (including systems pre-connected to Foley catheters) and sterile 4l irrigation bags - a complete list of affected product is attached). In certain units, there is potential that the connector between the catheter and the bag may be blocked. If this were to occur, urine would not drain into the bag which may result in urine retention in the bladder. Urine retention may necessitate medical intervention additional to routine care. The bag would need to be changed more often and the risk of developing an infection if standard of care were neglected may increase.

To address any potential risk of harm, the affected product (which may be identified by the lot numbers using the identification procedure specified below) is being recalled.

This recall covers the lot numbers as specified in the attached sheet.

Identification Procedure

Other than product lot number, there is no discernable difference between the packaging of the recalled product and unaffected product. The lot number can be found on the carton, box, and the individual peel pack/pouch.

If the lot number is not available, the recalled product cannot be identified through visual inspection. It can only be identified through testing prior to use.

Instruction on action to be taken by the End User:
Our records show that you have taken delivery of the affected products. Please follow the steps below:

1. Please stop the use of all products from the affected LOTs, which you may have.
2. Check stock and complete the enclosed form which should be forwarded to your distributor by 31st January 2011.
3. Return all affected products to your distributor for credit by 31st January 2011.
4. Please mark all returned product clearly with: "Unomedical Urine Drainage Bags Recalled Products from Your Name Here"

Transmission of this Field Safety Notice:
Unomedical apologises for any inconvenience this may cause and requests that you share this Notice with all relevant urine drainage bag customers/users. If you have any questions, please contact your distributor or local Unomedical representative.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Contact reference person relating to this letter:

Bente Blauenfeldt
Customer Service Coordinator

Unomedical A/S
Birkerød Kongevej 2
3460 Birkerød
DENMARK

Tlf: + 45 48 10 30 36
Fax: + 45 48 10 30 00
E-mail: bente.blauenfeldt@convatec.com

For questions relating to your orders or replacement products, please contact your local Unomedical representative.

RECALL
CONFIRMATION FORM FOR END-USERS

Consignee of the device:

NAME:	ADDRESS:	QUANTITY:

The following device(s) have been forwarded to you:

REF:	DEVICE:	LOT No:	QUANTITY:

The recipient confirms (please, tick off as applicable):

_____ that none of the devices mentioned above are in my possession.

_____ that some of the devices mentioned above remain in my possession.
They will be returned as per the instructions given by the distributor.

Number/ Lot(s) to be returned:_____ pieces

_____ _____ _____
NAME (CAPITAL LETTERS) AND POSITION SIGNATURE DATE

_____
ADDRESS

This form has been submitted by a representative of the distributor:

_____ _____ _____
NAME SIGNATURE DATE