IRISH MEDICINES BOARD

Notice Information: - Recall
19 July 2011

Part 1. Product Information

a)	Title:	Unomedical Sterile Urine Drainage Bags
b)	Product Name/Type:	Unomedical Sterile Urine Drainage Bags
c)	Reference:	IMB Safety Notice: SN2011(18)
d)	Manufacturer/Supplier:	Unomedical A/S

Part 2. Target Audience

a)	Target Audience:	Theatre and Nursing Staff Procurement Managers Nursing Managers Hospital Managers / CEOs Clinical Directors Risk Managers Medical Device Distributors Clinical / Biomedical Engineers Pharmacists Members of the Public

Part 3. Problem/Issue

a)	Problem/Issue:	Unomedical A/S has become aware that in certain sterile urine drainage bags, there is potential that the connector between the catheter and bag may be blocked.

Part 4. Background Information

a)	Background Information:	Unomedical A/S has confirmed that this issue is limited to specific model and lot numbers (see attached field safety notice). If this defect is present, it is possible that 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. Unomedical A/S has published a field safety notice (FSN) and has undertaken a recall of the affected product lots.

Part 5. Action to be taken

a)	Action to be taken:	The manufacturer and the distributors of this device in Ireland have been unsuccessful in their attempts to locate all devices affected by this field safety corrective action (FSCA). The IMB advises that users: • Follow the manufacturer's recommendations as outlined in the attached FSN. • Identify the affected devices in your facility and contact the manufacturer to arrange for return.

Part 6. Enquiries

a)	All enquiries should be made to:	Enquiries to the manufacturer should be addressed to: Sara Collins Customer Service Supervisor Unomedical Ltd First Floor, Unit 3 West Wing Brooklands, Moons Moat Drive Redditch, Worcestershire B98 9DW United Kingdom Telephone: +44 1527 583622 Fax: +44 1527 591198 E-mail: sara.collins@convatec.com All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: vigilance@imb.ie Website: www.imb.ie Please click here to download a PDF Version of the Safety Notice: SN

Please click here to download a PDF Version of the Safety Notice: SN2011(18)

Please click here to download a PDF Version of the Field Safety Notice