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NOTICE**

Unomedical Sterile Urine Drainage Bags

IMB Safety Notice: SN2011(18)
Circulation Date: 19 July 2011

MANUFACTURER/SUPPLIER

Unomedical A/S

TARGET GROUPS

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

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.

BACKGROUND

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.

ACTION OR RECOMMENDATIONS

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.

S A F E T Y

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ENQUIRIES

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