HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Klerpack BD Syringe Multi-Pack

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2016(26) **Issue Date: 12 September 2016**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Ecolab Ltd.	V29189

ISSUE
Ecolab Ltd. has identified that the sterile packaging of the Klerpack BD Syringe Multi-Pack may contain small holes in the film of the pouch. If holes are present, the package integrity is compromised and there is a risk that the syringe may no longer be sterile. The issue affects a number of different product codes and lot numbers. Please refer to the Field Safety Notice (FSN) issued by Ecolab Ltd. for specific details. We understand that these syringes have been supplied to the Irish market by multiple distributors.

ACTION OR RECOMMENDATIONS

The HPRA advise that users:

1 Follow the actions outlined by the manufacturer in the accompanying FSN.

2 Immediately examine your stock and quarantine affected devices. Refer to the FSN for a list of affected product codes and respective lot numbers.

3 Pass the manufacturer's FSN to all those who need to be aware of it within your organisation. Forward a copy of the FSN to any other organisations to whom affected devices have been transferred.

4 Forward a copy of this HPRA Safety Notice to all relevant personnel.

5 Forward a copy of this HPRA Safety Notice to any other persons / organisations where these devices have been transferred.

6 Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Accident & Emergency Departments
Biomedical Engineers
Clinical / Medical Directors
Clinical Nurse Managers
Community pharmacists
Community users
Critical Care units / Intensive Care units
Day surgery units
General public
Healthcare professionals who use these devices
Hospital managers / CEOs
Hospital personnel
Hospital pharmacies / pharmacists
HSE National Ambulance Service
Infusion clinics / Infusion Day units
Laboratory directors / managers
Laboratory technicians
Nursing staff
Outpatient departments
Paramedics / advanced paramedics
Community pharmacies / pharmacists
Private ambulance services
Product compounding centres / facilities
Public and private hospitals
Public Health nurses
Purchasing managers
Risk managers
Stores / supplies managers
Theatres
Voluntary / auxiliary ambulance services

BACKGROUND

Ecolab Ltd. identified during internal testing that small holes may be present in the film of the pouch of the device packaging.

Please refer to the manufacturer's FSN for details of specific product codes and lot numbers affected.

The HPRA is issuing this safety notice to raise awareness of this issue.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Ecolab Ltd.
PO Box 11, Winnington Avenue
Northwich, Cheshire
CW8 4DX
Great Britain

Customer Service, Ecolab Ltd
Telephone: +44 (0) 2920 854 390
Fax: +44 (0) 2920 854 391
E-mail: infocc@ecolab.com
Website:
http://ecolabcc.com/index.php

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie