HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

PVC Paediatric Enteral Feeding Tube

Priority 2 – Warning

HPRA Safety Notice: SN2015(29) **Issue Date: 5 November 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Pacific Hospital Supply Co. Ltd. (PAHSCO)	V26009

ISSUE

The HPRA has been notified of a **recall** initiated by the manufacturer, Pacific Hospital Supply Co. Ltd. (PAHSCO), for PVC paediatric enteral feeding tubes. The manufacturer became aware of a risk of stiffness with PVC Paediatric Enteral Feeding Tube.

The manufacturer has confirmed that these devices have also been placed on the Irish market. This issue affects Paediatric Enteral Feeding Tubes with article numbers:
I05105, I05106, I05108, I05110, I05131, I05132, I05134, I05135, I05204, I05205, I05206, I05208, I05210, I05220, I05221, I05222, I05224, I05225, I05232, I05234, I05235.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Should immediately stop using these devices.

2 Check and quarantine all affected stock. Follow the actions outlined in the attached PHASCO field safety notice (FSN).

3 Forward this Safety Notice to other departments or facilities in accordance with your procedures.

4 Contact your PAHSCO representative with any queries and / or concerns.

5 Report any adverse events / incidents associated with this device to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs	Anaesthetic Officers
Risk Managers	Accident & Emergency Departments
Clinical / Medical Directors	Day surgery units
Risk Managers	Paediatric wards
Clinical Nurse Managers	Oncology units
Nursing staff	Paediatric intensive care units
Purchasing Managers	Neonatal units
Procurement	Theatres
Hospital personnel	All wards
Palliative Care Units	Healthcare professionals who use these devices
Intensive Care Units	

BACKGROUND

The manufacturer became aware of an incident that occurred in Norway where bleeding occurred in a premature infant resulting in abdominal surgery. The PVC feeding tube was found to become very stiff, deformed and discoloured during use.

The manufacturer has issued a FSN advising of this issue and recalling all affected devices from the market. See attached FSN for affected product codes and specifications.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

Pacific Hospital Supply Co Ltd
4F, no 160, Daye Road,
Beitou Dist. Taipei 112
Taiwan

Telephone: +866 2 2895 5050
Fax: +866 2 2897 8282
E-mail: N/A
Website: N/A

Enquiries to the **authorised representative** should be addressed to:

Mdi Europa GmbH
Langenhagener Str. 71
D-30855 Hannover-Langenhagen
Germany

Telephone: +49-511-3908 95313
Fax: +49-511-3908 9539
E-mail: martina.giesemann@mdieuropa.com
Website: www.mdi-europa.com

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

Irish Hospital Supplies
Beechwood Close
Boghall Road
Bray, Wicklow
Ireland

Telephone: +353 1 2829016
Fax: +353 1 2829957
E-mail: ocarr@ihs.ie
Website: N/A

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