

Safety Notice

Medical Devices

Feeding Tubes, Nelaton Catheters, Levins Tubes, Rectal Catheter, Ryles Tubes, Suction Catheters, Stomach Tubes, Medical Packs.

Priority 2 – Warning

HPRA Safety Notice: SN2019(28)

Issue Date: 15th August 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Pennine Healthcare	V40123

ISSUE
Pennine Healthcare has issued the recall of multiple lots of the above products. The full list of impacted product codes and lots are listed in the attached Field Safety Notice (FSN).

ACTION OR RECOMMENDATIONS
The HPRA advises that users:
<ol style="list-style-type: none">1 Read and follow the instructions in the manufacturer's Field Safety Notice.2 Determine if your stock contains LOTs impacted by this recall, as listed in the FSN, and quarantine affected product accordingly.3 Complete and return the Field Safety Notice Acknowledgement Form, confirming affected product details, if applicable.

- 4 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
- 5 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Hospitals Clinics General practitioners Community care managers Community nurses Community therapists	Medical Directors Nursing Homes Private medical practitioners Risk managers Supplies managers Carers
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BACKGROUND

The manufacturer Pennine Healthcare has identified that there is a possibility that the products detailed in the Field Safety Notice may not have been manufactured with the correct eyes (holes) punched into the tube. The defect in the products should be visible to a trained user, however, if the user missed the defect, it would mean the products would not perform to the required expectations. There is a potential for serious harm should an alternative non-defective device not be available at the time.

The HPRA is issuing this Safety Notice to raise awareness of this issue. To date no incidents have been reported to the HPRA in relation to this issue.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Pennine Healthcare Ltd.,
City Gate, London Road, Derby, DE224 8WY

Telephone: +44(0)1332 794880
E-mail: info@penninehealthcare.co.uk
Website: penninehealthcare.co.uk

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

TP Whelehan /Whelehan Surgical,
Suite 12, Bunkilla Plaza, Bracetown Business Park,
Clonnee, Dublin 15.

Telephone: (01) 806 8600
E-mail: info@tpwhelehan.ie
Website: whelehansurgical.ie

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
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie