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Medical Device / Equipment **RECALL**

Date Issued : 15th May 2008

Ref:MDB/R/2008/008

IMMEDIATE ACTION	√
ACTION	
UPDATE	
INFORMATION REQUEST	

PRODUCT	Robertshaw endobronchial tubes (PVC, disposable) all sizes – manufactured by Phoenix Medical, a P3 Medical Ltd company. <i>*Please refer to Appendix 1 for details.</i>
CLASS	n/a
USE	It is an endobronchial tube with introducing stylet, it is a double lumen tube used during thoracic surgery where it is necessary to isolate one lung from the other.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Medicines and Healthcare products Regulatory Agency, United Kingdom’s website, Date issued: 14 th May 2008
ALERTING / RECALLING FIRM	Phoenix Medical, a P3 Medical Ltd company
REASON	Due to a manufacturing defect there is a risk of damage to the intubating stylet on its removal from the endobronchial tube. The resulting plastic debris may enter the patient’s airway. The manufacturer has recalled all stock supplied to the healthcare facilities under NHS in the United Kingdom.
SCENARIO IN MALAYSIA	No details available at this moment. Please check whether the device is available and contact the distributor.

ACTION	<p><i>Action or Recommendations For Healthcare Professionals</i></p> <ul style="list-style-type: none"> • Ensure that all relevant staff in your institution are informed of this safety alert/warning especially the anaesthetists, operating department practitioners and anaesthetic nurse. • Determine if you have the affected products • Locate and monitor the usage of the affected products • Determine how much of this product has been used • Follow the distributor / manufacturers recommendations for quarantine and disposal of product
RECOMMENDATION	<p>Users of the abovementioned device should contact the distributors/supplier of this device (if available) and inform the Medical Device Bureau, Ministry of Health Malaysia providing the following information:-</p> <ol style="list-style-type: none"> a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES IN MALAYSIA	<p>Currently No Information Available</p>
REFERENCES	<p>http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON015416</p>

Appendix 1

List of Robertshaw endobronchial tubes that are being recalled. Note that the lot numbers are a date code in the format dd-mm-yyyy or yyyy-mm-dd

Product code	Description	Lot number
PRS-26L	Endobronchial tube, 26ch Left	All dates before 2008
PRS-26R	Endobronchial tube, 26ch Right	All dates before 2008
PRS-28L	Endobronchial tube, 28ch Left	All dates before 2008
PRS-28R	Endobronchial tube, 28ch Right	All dates before 2008
PRS-32L	Endobronchial tube, 32ch Left	All dates before 2008
PRS-32R	Endobronchial tube, 32ch Right	All dates before 2008
PRS-35L	Endobronchial tube, 35ch Left	All dates before 2008
PRS-35R	Endobronchial tube, 35ch Right	All dates before 2008
PRS-37L	Endobronchial tube, 37ch Left	All dates before 2008
PRS-37R	Endobronchial tube, 37ch Right	All dates before 2008
PRS-39L	Endobronchial tube, 39ch Left	All dates before 2008
PRS-39R	Endobronchial tube, 39ch Right	All dates before 2008
PRS-41L	Endobronchial tube, 41ch Left	All dates before 2008
PRS-41R	Endobronchial tube, 41ch Right	All dates before 2008