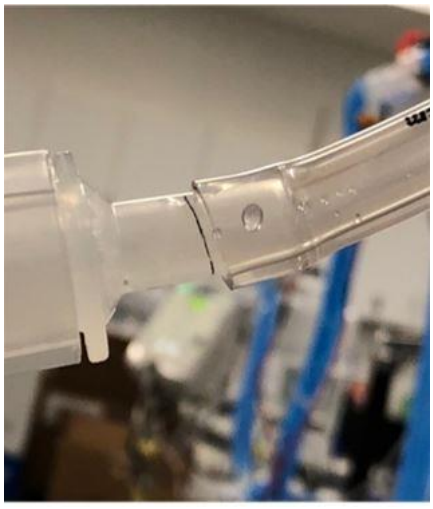
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Sheridan Close Fitting Endotracheal Tube
Sheridan Endotracheal Tube
Sheridan HVT Endotracheal Tube
Sheridan HVT EZ-Endo Endotracheal Tube
Sheridan Preformed Endotracheal Tube
Sheridan Uncuffed Endotracheal Tube



Priority 1 – For Immediate Action

HPRA Safety Notice: SN2019(20) **Issue Date: 31st May 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Teleflex Medical	V40185

ISSUE

Teleflex Medical is initiating a recall due to reported complaints indicating that there is an increased incidence of specific lots of the 15 mm Sheridan connector becoming disconnected from the Endotracheal tube.

Disconnection of patients from the breathing circuit in this manner may result in insufficient oxygenation, requiring urgent medical intervention and may result in hypoxia.

ACTION OR RECOMMENDATIONS

The HPRA advises that users follow the instructions provided by the manufacturer:

For product already in use with patients:

1 Ensure the 15 mm connector is seated firmly in the Endotracheal Tube to prevent disconnection during use as per Instructions for Use (IFU).

2 Should disconnection occur, reconnect the two components promptly and securely in the manner described in the IFU or consider replacing the connector, making sure to evaluate the risks associated with reintubation.

For unused product:

1 Check product inventory for product from affected lot numbers as detailed in Appendix 2 of the accompanying field safety notice (FSN). **Cease use and distribution of impacted product and quarantine immediately.**

2 Acknowledge receipt of the FSN using the manufacturer's acknowledgement form if you have not already done so.

Additionally, the HPRA advises that users:

3 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.

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

TARGET GROUPS

Hospitals Clinics A&E consultants A&E nurses Intensive care Staff Coronary care units Resuscitation officer	Clinical Engineers Theatre managers Anaesthesiologists Anaesthetic Nurses

BACKGROUND

There have been 192 incidents worldwide relating to this issue (<0.0025% of all in scope distributed product). Two deaths and one injury have been reported (outside Ireland). In most reported cases, detachment of the connector was identified by clinical personnel or via eventual decrease in ventilator circuit pressure which triggered ventilator alarms.
Product from the following affected lot numbers is known to have been supplied to the market in Ireland:

Product code	Lot Number
5-11112	73A1700646
	73A1800671
	73C1700238
	73D1800138
	73F1800174
	73H1700041
	73J1700292
	73K1600369
	73K1800172

Please see the accompanying manufacturer's FSN for further information.
The HPRA is issuing this Safety Notice to raise awareness of this issue.

AUTHORISED REPRESENTATIVE CONTACT INFORMATION

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

Teleflex Medical,
IDA Business & Technology Park,
Dublin Road,
Athlone,
Co. Westmeath,
Ireland.

Telephone: 090 646 0815
E-mail: globalfca@teleflex.com
Website: https://www.teleflex.com/emea/

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