HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Intraluminal Staplers

Product Codes: ECS21A, ECS25A, ECS29A, ECS33A, CDH21A, CDH25A, CDH29A, CDH33A (specific lots)

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2019(11) **Issue Date: 11 April 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Ethicon Endo-Surgery LLC, USA	V39460

ISSUE
Ethicon have confirmed occurrence of uncut washers and malformed staples with their intraluminal circular staplers, which can compromise staple line integrity. If a problem with the staple line is not adequately addressed or is not recognised, there is a potential risk of postoperative anastomotic leak, gastrointestinal injury, haemorrhage, or haemorrhagic shock. Ethicon requests that healthcare professionals **return all products subject to this field safety notice, if alternative products are available**. Ethicon recognises due to worldwide supply issues with intraluminal staplers, alternative products may not be available. If alternative products are not available to complete required surgeries, it is critical to adhere to the instructions outlined in the field safety notice. Ethicon have advised that there were 422 affected units placed on the Irish market. No complaints have been reported to date from the Irish market. Based on Ethicon's analysis of complaints received to date and estimated device usage, the predicted occurrence of complaints for malformed staples has increased but is expected to remain below 0.1%. Please see the accompanying manufacturer's field safety notice for further information and a list of affected lot numbers.

ACTION OR RECOMMENDATIONS

The HPRA advises that healthcare professionals:

1. Refer to the accompanying field safety notice and follow the instructions provided by the manufacturer.

2. Forward a copy of this safety notice to all relevant personnel within your organisation or to any other organisations these devices have been transferred to.

3. Acknowledge receipt of the field safety notice if you have not already done so.

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

TARGET GROUPS

Hospital Managers / CEOs	ICU Staff
GI / Colorectal Surgeons	Clinical Nurse Managers
General Surgeons	Risk Managers
A&E Consultants	Procurement Managers
Theatre Staff	Stores / Supplies Staff

MANUFACTURER CONTACT INFORMATION

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

Johnson & Johnson Medical Devices (UK/Ireland)
St. Anthony's Road
Leeds LS11 8DT
United Kingdom

Telephone: +44-113-387-6261
E-mail: MDFieldActionsUKIrl@its.jnj.com

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