

Safety Notice

Medical Devices

Endo GIA Surgical Stapling Single Use Loading Units, Tri-Staple 2.0 Intelligent Reloads and Cartridges

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2019(22)

Issue Date: 14th June 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Medtronic Ltd.	V40103

ISSUE

Medtronic is recalling specific production lots of its Endo GIA Surgical Stapling Single Use Loading Units, Tri-Staple 2.0 Intelligent Reloads and Cartridges.

This recall is being conducted due to the potential for a device to be missing one of two pin components that maintain alignment of the device jaws. This potential issue was identified during in-process quality testing at the manufacturing facility.

Use of a product without a pin may result in incomplete staple formation, potentially leading to bleeding, anastomotic leak, peritonitis, or pneumothorax which can result in the potential for infection and/or sepsis.

Please see the accompanying manufacturer's field safety notice (FSN) for further information and a list of affected lot numbers.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSN and follow the instructions provided.
2. Ensure that affected product is removed from use, quarantined and returned to the supplier/ manufacturer.
3. Acknowledge receipt of the FSN to the supplier.

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

TARGET GROUPS

General Surgeons GI / Colorectal Surgeons Obstetricians and Gynaecologists Abdominal Surgeons Hepatobiliary Surgeons Paediatric Surgeons Cardiothoracic Surgeons A&E Consultants ICU Staff Directors of nursing Clinical Nurse Managers All surgical wards and theatres Theatre Staff Theatre Managers	Hospital Managers / CEOs Risk Managers Supplies managers Procurement / Purchasing Managers Stores / Supplies Staff
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BACKGROUND

The Endo GIA™ Ultra Universal staplers have applications in abdominal, gynaecologic, paediatric and thoracic surgery for resection, transection and creation of anastomosis. It may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Description of Issue:

There is a potential for a device to be missing one of two pin components that maintain alignment of the device jaws.

The affected devices were distributed between April 2014 and April 2019. This issue was identified by Medtronic during in-process quality testing at the manufacturing facility. Manufacturing process improvements have been implemented to address the issue.

The hazardous situation is that the use of a device without the drive pin installed could result in incomplete staple formation which can potentially lead to bleeding, anastomotic leak, peritonitis, or pneumothorax.

As a result of this issue, Medtronic is recalling specific production lots of its Endo GIA Surgical Stapling Single Use Loading Units, Tri-Staple 2.0 Intelligent Reloads and Cartridges.

The HPRA is issuing this Safety Notice to raise awareness of this issue.

MANUFACTURER / AUTHORISED REPRESENTATIVE CONTACT INFORMATION

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

Medtronic Ltd.

Vigilance.eu@medtronic.com

Building 9, Hatters Lane, Croxley Park

Watford

UK

WD18 8WW

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

Covidien Ireland Ltd.

Vigilance.eu@medtronic.com

IDA Business & Technology Park

Tullamore

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority

Telephone: +353-1-6764971

Kevin O'Malley House

E-mail: devicesafety@hpra.ie

Earlsfort Centre

Website: www.hpra.ie

Earlsfort Terrace

Dublin 2