HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Covidien Endo GIA™ Auto Suture™ universal articulating loading units

Product Codes: 030450, 030451, 030452, 033453, 030454, 030455, 030457, 030458

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2020(12) **Issue Date: 26th August 2020**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Medtronic, USA	V44521

ISSUE
Medtronic is voluntarily recalling specific production lots of its Covidien Endo GIA™ Auto Suture™ universal articulating loading units due to the occurrence of malformed staples which can compromise staple line integrity. Medtronic has indicated that this issue can lead to an increased risk of significant haemorrhage and other immediate and delayed complications, which may require urgent conversion to open surgery. No complaints have been reported to date from the Irish market. The HPRA is issuing this Safety Notice to raise awareness of the recall action as these devices are used in a wide range of surgical subspecialties and use of malformed staples carries an increased risk of severe or life-threatening complications. Medtronic has advised that there are 2,253 units within the scope of this field safety corrective action placed on the Irish market and the HPRA wishes to alert users of a potential for device shortages in the immediate term due to the large quantity of devices being recalled.

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 healthcare professionals:

1. Refer to the accompanying field safety notice and follow the instructions provided by the manufacturer.
2. As described in the FSN, please examine your inventory immediately, remove and quarantine any unexpired affected devices.
3. 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.
4. Acknowledge receipt of the field safety notice if you have not already done so.
5. Contact the manufacturer using the contact details provided in the FSN if you have any difficulty in identifying the affected devices.
6. Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs	**Emergency Medicine Consultants**
Cardiothoracic Surgeons	Theatre Staff
Vascular Surgeons	ICU Staff
Colorectal Surgeons	Clinical Nurse Managers
Hepatobiliary Surgeons	Risk Managers
Paediatric Surgeons	Procurement Managers
Urologists	Stores / Supplies Staff
Obstetricians/Gynaecologists	
General Surgeons	

BACKGROUND

Medtronic has identified a potential for a manufacturing assembly error that can contribute to staple malformation and use of a product with this assembly error may result in incomplete staple formation.

Use of malformed staples in surgical procedures increases the risk of serious/life-threatening complications, including significant haemorrhage such as haemothorax and haemoperitoneum in thoracoscopic and laparoscopic cases. The potential also exists for bleeding, anastomotic leak, pneumothorax, and other delayed secondary complications including infection, peritonitis, sepsis, and an increased risk of mortality. Urgent conversion to open surgery may also be required.

Medtronic has confirmed that the scope of this recall is limited to the Covidien Endo GIA™ AutoSuture™ universal articulating loading units and that the affected devices were distributed between June 2017 and July 2020.

MANUFACTURER CONTACT INFORMATION

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

Covidien llc,
15 Hampshire Street, Mansfield, USA.
MA 02048
United States of America

E-mail: rs.vigilance.eu@medtronic.com

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

Covidien Ireland Ltd.
IDA Business and Technology Park,
Tullamore,
Ireland.

Telephone: +353 87 8255 185
E-mail: rs.vigilance.eu@medtronic.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