HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Covidien Endo GIA™ Articulating Reloads.

Priority 2 – Warning

HPRA Safety Notice: SN2018(20) **Issue Date: 06th June 2018**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Medtronic / Covidien	V35715

ISSUE
Medtronic has initiated a voluntary recall of the above product due to the potential for a device to be misassembled. Use of a misassembled device may result in failure to form a staple line when tissue is divided, leading to bleeding or leakage of luminal contents. Medtronic initially communicated this recall in early May, FSN 1 attached. The scope of the recall was then expanded to include additional products which was communicated in a second updated communication in late May FSN 2 attached.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Ensure that you have received both of the manufacturer's field safety notices (FSN1 and FSN 2) attached. 2 Ensure that you read and follow the instructions provided in the manufacturer's field safety notice (FSN) and immediately discontinue the use of the affected product detailed in the FSNs. 3 Ensure that affected product is quarantined and returned to the manufacturer. 4 Ensure that all relevant staff in your organisation are aware of these FSNs. 5 Acknowledge receipt of the FSN if you have not already done so. 6 Report any concerns regarding this device or incidents involving this device to the manufacturer and the HPRA.

TARGET GROUPS	
Directors of nursing General surgeons Abdominal surgeons Thoracic surgeons Paediatric surgeons Gynaecological surgeons General surgery Medical directors Nursing director	Risk managers Supplies managers Theatre managers

BACKGROUND

The Endo GIA™ Tri-Staple™ Technology Reloads have application in open or minimally invasive general abdominal, gynaecologic, and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, e.g. low anterior resection. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

Medtronic / Covidien have initiated a recall of the above product due to the potential for a device to be misassembled. Use of a misassembled device may result in failure to form a staple line when tissue is divided, leading to bleeding or leakage of luminal contents. Medtronic has received five reports of injury related to this issue. This action was communicated in early May, FSN 1 attached.

The scope of the recall was expanded to include additional codes and lots. This updated action was communicated in late May, FSN 2 attached.

MANUFACTURER CONTACT INFORMATION

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

Medtronic Limited
Building 9
Hatters Lane
Croxley Park
Watford
WD18 8WW

Telephone: +353- 1-5111444
E-mail: 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
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie