



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



23 APR 2021

**FDA ADVISORY**  
No. **2021-0809**

**TO: ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

**SUBJECT: Voluntary Recall of Covidien Endo GIA™ Auto Suture™ Universal Articulating Loading Units**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Covidien Endo GIA™ Auto Suture™ Universal Articulating Loading Units with FDA registration number, DVR-5906, imported and distributed by Medtronic Philippines Inc.:

Product Description	Item Code #	ItemGrp#	Lot/Batch #	Quantity
RODICUL TR ENDO GIA 30-2.5 DLU	030451	MDT EMID Supplies	T9E081X	12 pcs
Endo Gia Universal Articulating Loading Unit 30mm-2.5mm	030451	MDT EMID Supplies	T9G037X	12 pcs
Endo Gia Universal Articulating Loading Unit 30mm-2.5mm	030451	MDT EMID Supplies	T9G029X	6 pcs
Endo Gia Universal Articulating Loading Unit 30mm-2.5mm	030451	MDT EMID Supplies	T9G029X	12 pcs
ENDO GIA R/OR 30 3.5MM	030452	MDT EMID Supplies	T81087X	6 pcs
Endo GIA Roticulator 45mm 2.0mm	030453	MDT EMID Supplies	T7L033X	12 pcs
Endo GIA Roticulator 45mm 2.0mm	030453	MDT EMID Supplies	T7L033X	12 pcs
Endo GIA Roticulator 45mm 3.5mm	030455	MDT EMID Supplies	T9F048X	12 pcs
Endo GIA Roticulator 45mm 3.5mm	030455	MDT EMID Supplies	T8K048X	8 pcs
Endo GIA Roticulator 45mm 3.5mm	030455	MDT EMID Supplies	T9F048X	12 pcs



Endo GIA Roticulator 45mm 3.5mm	030455	MDT EMID Supplies	T9F048X	6 pcs
Endo GIA roticulator 45mm 3.5mm	030455	MDT EMID Supplies	T9H146X	6 pcs
Endo GIA Roticulator 45mm 3.5mm	030455	MDT EMID Supplies	T9M049X	6 pcs
ENDO GIA R/OR 60 2.5MM X6	030457	MDT EMID Supplies	T9D055X	12 pcs
ENDO GIA R/OR 60 2.5MM X6	030457	MDT EMID Supplies	T9E025X	12 pcs
Endo GIA Roticulator 60mm 3.5mm	030458	MDT EMID Supplies	T9G159X	6 pcs
Endo GIA Roticulator 60mm 3.5mm	030458	MDT EMID Supplies	T9G159X	6 pcs
Endo GIA Roticulator 60mm 3.5mm	030458	MDT EMID Supplies	T9J030X	12 pcs
Endo GIA Roticulator 60mm 3.5mm	030458	MDT EMID Supplies	T9L075X	12 pcs

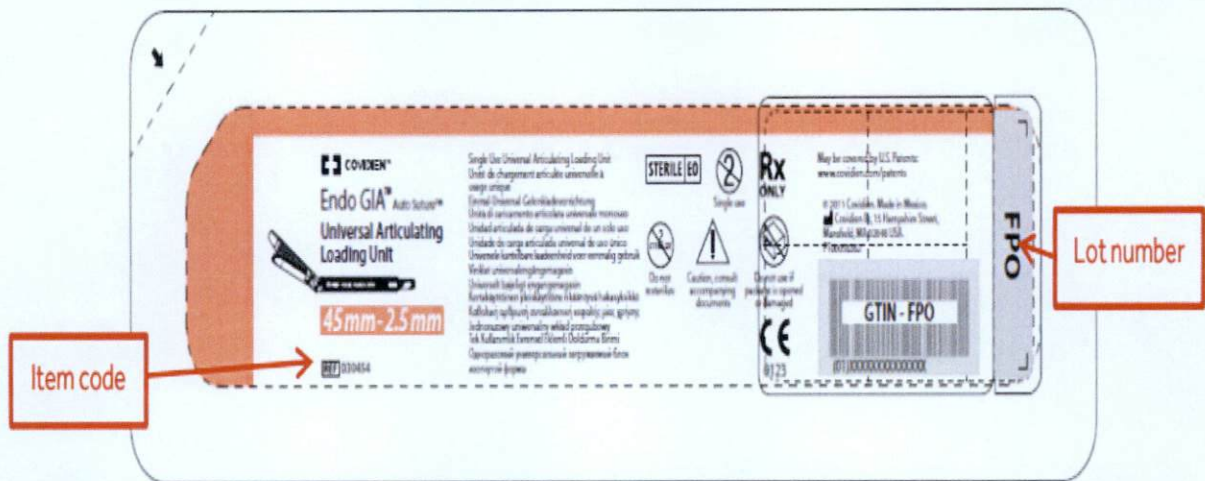


Figure 1. Photo of Affected Covidien Endo GIA™ Auto Suture™ Universal Articulating Loading Unit, 45mm-2.5mm

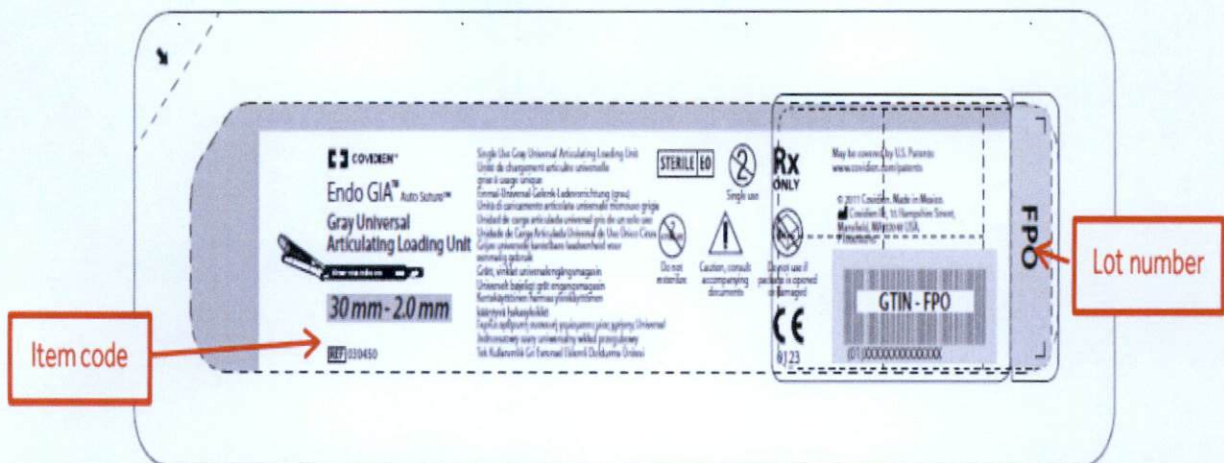


Figure 2. Photo of Affected Covidien Endo GIA™ Auto Suture™ Universal Articulating Loading Unit, 30mm-2.0mm



Figure 3. Photo of Affected Covidien Endo GIA™ Auto Suture™ Universal Articulating Loading Units, 60mm-3.5mm

Medtronic Philippines Inc. initiated the voluntary recall of the above-mentioned specific lots/batches of Covidien Endo GIA™ Auto Suture™ universal articulating loading units in response to one confirmed customer report that the device staples were not properly formed upon application preventing adequate hemostasis. Investigation has shown this is due to manufacturing assembly error that can contribute to staple malformation.

The most common potential also exists for bleeding, anastomotic leak, pneumothorax or other delayed secondary complication including infection, peritonitis, sepsis, and increased risk of mortality. Manufacturing process improvements have been implemented to remediate this issue.

In light of the foregoing, all concerned healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batches of Covidien Endo GIA™ Auto Suture™ universal articulating loading units.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at [cdrhr@fda.gov.ph](mailto:cdrhr@fda.gov.ph), or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
 Director General