Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2019-523

17 DEC 2019

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Voluntary Recall of Endo GIA™ Articulating Reload with Tri-Staple™ Technology**

The Food and Drug Administration (FDA) warns all healthcare professional and the general public on the voluntary recall of Endo GIA™ Articulating Reload with Tri-Staple™ Technology with MDR No. 00768, imported and distributed by Medtronic Philippines Inc.:

Product Name	Product Code	Lot Number
Endo GIA™ Articulating Reload with Tri-Staple™ Technology	EGIA60AMT	N5G0186KX
		N5J0492KX
		N5J0775KX
		N5M0769KX
		N5M0582KX
		N6C0972KX
		N6E0462KX
		N6E0600KX
		N6F0541KX

Figure 1. Endo GIA™ Articulating Reload with Tri-Staple™ Technology for recall

Medtronic Philippines Inc. has conducted the voluntary recall of the aforementioned product due to the potential absence of one of the two pin components that maintains the alignment of the device jaws. This potential issue was identified during the in-process quality testing at the manufacturing facility. The use of a product with missing pin may result in incomplete staple formation. This may cause bleeding, anastomotic leak, peritonitis, or pneumothorax which can result in the potential for infection and/or sepsis. Manufacturing process improvements have been implemented to address this issue. There have been no confirmed complaints associated with this recall.

In light of the foregoing, all concerned healthcare professional, establishment, and the general public is warned to discontinue further use, sale, and distribution of the said medical device.

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.

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

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 **cdrrhr@fda.gov.ph**, or call **(02) 857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

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Officer-in-Charge, Director General

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