



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2017-237**

09 AUG 2017

TO: THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS

SUBJECT: VOLUNTARY PRODCUCT RECALL OF PHYSIOMESH COMPOSITE MESH (MDR-00270)

The Food and Drug Administration informs the public that Johnson and Johnson (Phils.) Inc., the Marketing Authorization Holder (MAH), has voluntarily recalled, removed and destroyed ETHICON Physiomesh Flexible Composite Mesh – MDR-00270 (for laparoscopic use) from the Philippine market.

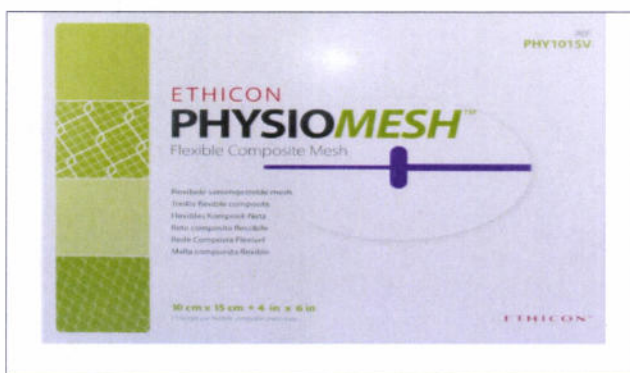


Figure 1. ETHICON Physiomesh Flexible Composite Mesh

The MAH conducted these activities at the request of the Ethicon Medical Safety Team after a review of unpublished data from two (2) large independent hernia registries (Herniated German Registry and Danish Hernia Database-DHDB). Based on the data, there are higher revision rates between Physiomesh flexible composite and other meshes in the registries after laparoscopic ventral hernia repair due to a multifactorial issue. Consequently, this discrepancy of Ethicon Physiomesh Composite Mesh product line has not been fully characterized. Thus, a worldwide device removal has been conducted and it is communicated to the U.S. Food and Drug Administration (US FDA).

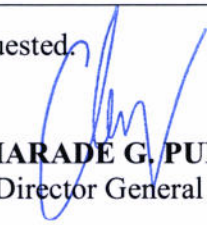
In coordination with the FDA Philippines, the recall, removal and destruction of the medical device has been completed. The summary of the affected batch of products recalled and destroyed are as follows:

Product Code	Batch Number
PHY1015V	HK8DGKB0
	JD8DCTB0
	JD8DKLB0
	JD8GDBB0
	JK8CCLC0
	JK8DSMC0
	JL8GRWD0



	JM8GPZD0 KB8BBJD0
PHY1515Q	EE8KHZA0 HL8DZHB0 HL8HKLB0 HP8BJZB0 JD8GDCB0 JE8BCXB0 JJ8DTXC0 JK8BKTC0 JK8CKZC0 JM8CQDD0 KA8HDQD0
PHY1520R	HL8DTWB0 JD8CRJB0 JD8DXHB0 JE8BRXB0 JM8CZZD0
PHY1520V	EB8HCTAO HP8DBKB0 JK8HCC0
PHY2025V	JB8BBXB0 JB8DDGB0 JB8DRGB0 JK8BSXC0 JL8BMHD0 JP8BMZD0 KA8GGKD0
PHY2030R	HM8DQWB0 HM8GCLB0 HP8CJBBO

Dissemination of the above information to all concerned is requested.


NELA CHARADE G. PUNO, R.Ph
 Director General



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