Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

07 MAR 2019

FDA ADVISORY
No. 2019-077

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

SUBJECT: **Voluntary Recall of PROXIMATE HCS Procedure for Prolapse and Hemorrhoids (PPH) Set, Codes PPH01 and PPH03**

All are hereby advised by the Food and Drug Administration (FDA) about the voluntary recall of the following lot numbers of **PROXIMATE HCS Procedure for Prolapse and Hemorrhoids (PPH) Set, Codes PPH01 and PPH03 (see figures 1, 2 and 3)**, with product registration number DVR-4945. The said products were imported and distributed by Johnson & Johnson (Philippines), Inc. with office address at Edison Rd., Bo. Ibayo, Parañaque City.

PRODUCT NAME	PRODUCT CODE	PRODUCT LOTS		
PROXIMATE HCS Hemorrhoidal Circular Stapler	**PPH01**	P9461W		
		P94K20		
PROXIMATE PPH Hemorrhoidal Circular Stapler	**PPH03**	P93K95	P9420Y	P94A4T
		P93L1M	P9420Z	P94D3N
		P93M3G	P9441H	P94F3Z
		P93T35	P9450L	P94G04
		P93T7F	P9463J	P94H5F
		P93W3M	P94765	P94J4W
		P93W3N	P9487Z	P94J80
		P93Y58	P94901	P94K2A
		P94117	P94A20	R9200Z

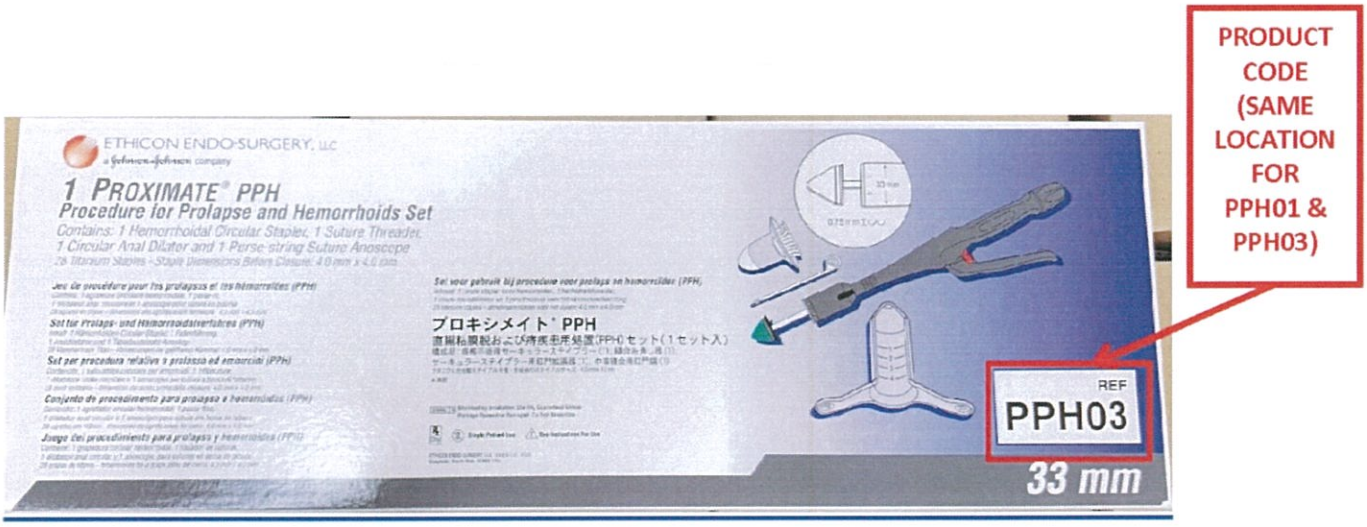

Figure 1: Front of Single Unit Carton of the Recalled Product

Figure 2: Label on Single Unit Carton of the Recalled Product

Figure 3: Top of the Primary Packaging of the Recalled Product

The above-stated medical device products are being voluntary recalled by Johnson & Johnson (Philippines), Inc. because the manufacturer, Ethicon Endo-Surgery, LLC, has confirmed that some devices contained in the affected lots may have been assembled without a washer. The medical assessment concluded that this situation may potentially cause bleeding or soft tissue injury during use as the device may not fully cut when fired.

Distributors, retailers, hospitals and all healthcare professionals/users are advised to discontinue further distribution, sale and use of the said affected medical device product.

Any suspected adverse reaction experienced from the use of the device but not limited to the lot stated above, should be reported immediately to FDA at telephone number (02) 857-1900 local 8301 or email us at cdrrhrprsdd@yahoo.com.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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