Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

18 DEC 2017

FDA ADVISORY
No. 2017-320

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS, ESTABLISHMENTS and GENERAL CONSUMING PUBLIC**

SUBJECT: **Public Health Warning Against the Use of Unregistered Medical Device (Sutures)**

The Food and Drug Administration (FDA) hereby advises all concerned healthcare professionals, establishments and general consuming public against the purchase and use of **ETHICON SUTURES** whose pictures appear below.

PRODUCT NAME	MANUFACTURER	BATCH NO.	REFERENCE CODE
Mersilk Black Braided Silk Suture	Johnson & Johnson Pakistan (Private) Limited	BN: 6906	Ethicon code N 537

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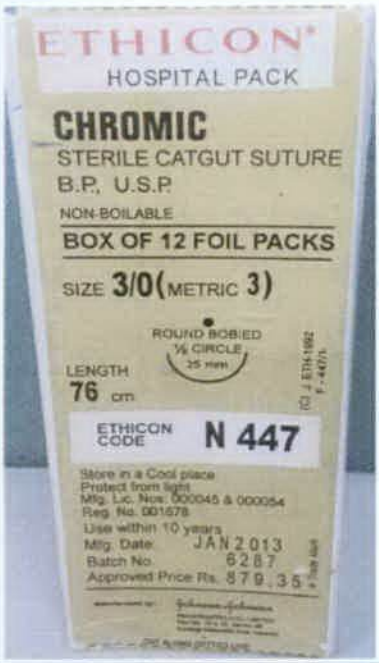
PRODUCT NAME	MANUFACTURER	BATCH NO.	REFERENCE CODE
Mersilk Black Braided Silk Suture	Johnson & Johnson Pakistan (Private) Limited	BN: 6875	Ethicon code N 570

PRODUCT NAME	MANUFACTURER	BATCH NO.	REFERENCE CODE
Mersilk Black Braided Silk Suture	Johnson & Johnson Pakistan (Private) Limited	BN: 6558	Ethicon code N 503



PRODUCT NAME	MANUFACTURER	BATCH NO.	REFERENCE CODE
Chronic Sterile Catgut Suture	Johnson & Johnson Pakistan (Private) Limited	BN: 6287	Ethicon code N 447

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device products has not gone through the registration process of the agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Pursuant to the provisions of Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", **the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered or misbranded are prohibited.**

The abovementioned products did not undergo the evaluation process of the FDA. Thus, the agency cannot guarantee their quality and safety.

Furthermore, FDA, in coordination with the Market Authorization Holder (MAH), Johnson & Johnson Philippines, Inc., has verified that the above-stated medical device products are counterfeit.

In this regard, the public is hereby advised not to purchase the above-mentioned violative products and to be vigilant against the medical device products that are not registered with the FDA.

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

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Development Division - Center for Device Regulation, Radiation Health and Research of the FDA at telephone no. (02) 857-1900 loc. 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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