Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-0521

08 MAR 2021

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Product Recall of W818 Silk Braided Surgical Needled Suture Sterile, Non-Absorbable Suture Size 8-0**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected product lots of W818 Silk Braided Surgical Needled Suture Sterile, Non-Absorbable Suture Size 8-0 with DVR No. 8024, manufactured by Ethicon LLC, imported and distributed by Johnson & Johnson (Phils.), Inc.:

Product Code	Description/Size	Product Lot
W818	W818 Mersilk 8/0 8MM Rev Cut D	KJQ327 KLH997 KPR661 LPH954 LPB629

Table 1. Affected lots of W818 Silk Braided Surgical Needled Suture Sterile, Non-Absorbable Suture Size 8-0

Figure 1. Photo of the Affected W818 Silk Braided Surgical Needled Suture Sterile, Non-Absorbable Suture Size 8-0

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Through routine product testing of the manufacturer, it has been determined that the affected lots of the abovementioned product may not meet the stringent individual and average requirements for tensile strength through full shelf life. With tensile strength below the requirement could potentially result in suture breakage during use. Thus, the manufacturer are unable to sustain a five (5) year shelf life claim of the said product.

Ethicon has not received any complaints or reports of Adverse Event or Injuries related to the afore mentioned issue and there is no anticipated patient safety impact.

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 affected lots of W818 Silk Braided Surgical Needled Suture Sterile, Non-Absorbable Suture Size 8-0.

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 **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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Director General

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