Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2018-044

14 FEB 2018

TO: THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS

SUBJECT: VOLUNTARY RECALL OF THE MALECOT NEPHROSTOMY CATHETERS WITH PRODUCT REGISTRATION MDR NO. 02508

Boston Scientific Philippines, Inc., the importer/distributor of Malecot Nephrostomy Catheters with the product registration number MDR-02508. has informed the Food and Drug Administration of the voluntary recall of the said product, specifically described as follows:

Product Description	Use	Material Number
Malecot Nephrostomy Catheter	Interventional Radiology or Urology	M001224110
		M0064101000
Malecot Nephrostomy Catheter		M0064101010
		M0064101040
Re-Entry TM Malecot Nephrostomy		M0064101050
Percutaneous Access Set		M0064201150

Said items are being voluntarily recalled due to reports of some catheters breaking at the mid-shaft bond during use. The bond is located where the end of the Malecot Nephrostomy catheter is bonded to the catheter shaft. Boston Scientific Philippines, Inc. has received seventeen (17) complaints for this issue since December 1, 2013. If the catheter bond break while inside the patient, the most common adverse health consequence would be additional intervention for endoscopic retrieval of the detached fragment. The most severe consequence that is reasonably expected to occur due to this issue is an additional open or laparoscopic procedure to remove the detached fragment. Lot and Ref numbers that are critical in determining the identity of the product for traceability. In the report to the FDA , Boston Scientific Philippines, Inc. disclosed that the affected lots were not distributed in the Philippine market as per their distribution list record.

At any rate, distributors, retailers and hospitals that have any lot of the stated medical device product are instructed to discontinue their further distribution, sale, and use. Furthermore, other distributors of said product shall coordinate with the FDA for the conduct of product recall. All consumers are likewise advised not to purchase or use the affected product lots.

Any suspected adverse reaction experienced or any incident of the same cases from the use of the device but not limited to the lots stated above, should be reported immediately to FDA at telephone no. (02) 857-1900 loc. 8301 or email us at cdrrhr_prsdd@fda.gov.ph.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, R.Ph
Director General

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