



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. **2017-084**

13 MAR 2017

TO: THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS

SUBJECT: HEALTH WARNING ON USING COVIDIEN VALLEYAB LAPAROSCOPIC HANDSET (FOUR-FUNCTION) WITH PRODUCT CODE E2750

All are hereby advised by the Food and Drug Administration (FDA) about the lots of the following laparoscopic handsets with product code E2750 distributed by Medtronic Philippines Inc. 32nd Street Bonifacio Global City, Fort Bonifacio Taguig City:

PRODUCT CODE	DESCRIPTION	Lot Numbers				
E2750	Valleylab Laparoscopic Handsets Four-Function	52990142X	53250061X	53610059X	60240065X	61220095X
		52990144X	53250063X	53610061X	60520098X	61220098X
		52990147X	53250065X	60240055X	60520104X	61300164X
		52990151X	53610053X	60240059X	60870064X	61540145X
		53250057X	53610055X	60240061X	61220093X	61540150X

The cited product are being voluntarily recalled by Medtronic Philippines Inc. because of the customer reports from its main manufacturer in other country on potential defect/malfunction of the device. In the report, the handset continues to operate upon release of the activation button. If it does not deactivate after release of activation button, it presents safety risk and possible health consequences like damage to the internal tissues.



Figure 1. Covidien Valleyab Laparoscopic Handset (Four-Function) with Product Code E2750



Distributors, retailers, hospitals that have any lot of the stated medical device product are instructed to discontinue further distribution, sale and use. 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



20170209113901