Medtronic

Medtronic Ireland Limited
Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
www.medtronic.ie
Tel: 01 511 1400
Fax: 01 807 7220

Urgent Field Safety Notice

Endo Clinch™ II and Endo Grasp™ Auto Suture™ Grasper 5mm

March 2019

Medtronic reference: FA858

Dear Physician or Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of the Covidien Endo Clinch™ II and Endo Grasp™ Auto Suture™ graspers 5mm.

Issue Description:
This voluntary recall is being conducted following a review of production records which indicate that the sterilization method used for these lots were not consistent with the labeling and the approved sterilization method. These products are labeled as sterilized with gamma radiation and in some cases, the devices were subjected to re-sterilization with ethylene oxide or a repeat gamma sterilization cycle. While re-sterilization with ethylene oxide does not impact device performance, it is not consistent with the product labeling. The use of products that have been re-sterilized using a gamma sterilization method may result in an increased potential for device failure and disengaged components. A resultant delay in treatment may occur while a replacement device is obtained and disengaged components are retrieved. The sterility of all affected devices is intact. There have been no complaint reports received for any of the affected lots.

This voluntary recall affects only the item codes and lots listed below.

Item Code	Description	Affected Lot Numbers		
174317	Covidien Endo Clinch™ II Auto Suture™ Grasper 5mm	P8D1333PRX	P8E1189PRX	P8F1239PRX
		P8D1334PRX	P8E1269PRX	P8F1307PRX
		P8D1614PRX	P8E1271PRX	P8F1448PRX
		P8D1615PRX	P8E1272PRX	P8F1452PRX
		P8D1616PRX	P8F0008PRX	P8F1480PRX
		P8E1143PRX	P8F1238PRX	P8F1545PRX
173030	Covidien Endo Grasp™ Auto Suture™ Grasper 5mm	P8D1335PRX	P8D1336PRX	P8D1605PRX

Medtronic

The following procedure kits include devices from the affected lots:

Item Code	Description	Affected Lots	
KIT00529H	BOX KIT00529H KIT COLECISTECTOMIA ACCESO	0217118756	
KIT00608	KIT00608 APENDICECTOMIA LAP X1	0217132887	
KIT00897	BOX KIT00897 KIT COLON IZQUIERDO	0217134109	
KIT2176CV	KIT2176CV BORNHOLM LAP INGUINAL HERNIA	0217123007	
KIT2951V	KIT2951V CHOLECYSTECT BORNHOLM	0217123010	
KIT2963	KIT2963 APPENDECTOMY KIT X1	0217123009	
KITM025	KITM025 M'LANDS MR NASSAR LAP CHOLEX1	0217127223	
LAPL1	BOX LAPL1 ZESTAW DO CHOLECYSTEKTOMII	0217118761	
KIT00599	KIT00599 LAPARO GENERICO X1	0217130753	0217130754
PST01134	BOX PST01134 LAP CHOLE KIT ST JOHN S	0217119261	0217119259
KIT00680	BOX KIT00680 KIT COLECISTECTOMIA	0217117857	0217117862
		0217117858	0217117863
		0217117859	0217117864
		0217117860	0217117865
		0217117861	0217118746
KIT00681	BOX KIT00681 KIT APENDICECTOMIA	0217118747	
		0217118748	
		0217118749	
		0217118750	

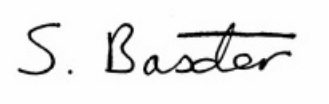
Required Actions:

1. Please immediately quarantine and discontinue use of the affected item codes and lots listed above.
2. Please return affected product to Medtronic. Your Medtronic Representative can assist you in returning the product.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at 01 511 1400.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager UK and Ireland

Medtronic

Attachment A