



رقم المحفوظات: ٣٧/٢٥
رقم الصادر: ١٢/١/٢٧٦٩
بيروت، في:
٢٨ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس. *Therapy tissue ablation*

الجهاز المعنى بالمتابعة:

- Therapy tissue ablation, Symplicity RDN catheter.
Trade Mark: Medtronic Limited
Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيّد بوجود خلل في عمل الصنف المذكور أعلاه لناحية فعالية التعقيم، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

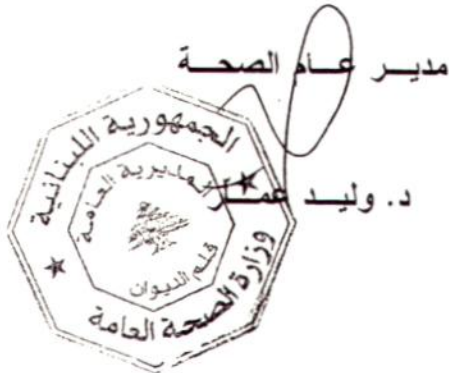
مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

دائرة البرامج والمشاريع

- المحفوظات



وثيقة مصدقة للأصل
بيروت في ٢٠ آب ٢٠١٢
دبس نسمة امانة السر
عناية طعن





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URGENT FIELD SAFETY NOTICE

Symplicity® Catheters Model RDN006

Product Recall

Medtronic ref : FA549

2nd August 2012

Dear Customer:

Medtronic has identified a potential issue with specific lots of the Symplicity® Catheter (Model RDN006). We have determined that a small number of pouches could be damaged, which could compromise product sterility. Medtronic is not aware of any adverse patient outcomes due to this issue, and our evaluation indicates an occurrence rate of 0.4% of approximately 4,000 distributed units (an estimated 16 catheters). This issue is specifically related to the packaging immediately surrounding the catheter (the pouch) and not the catheter itself. Medtronic has identified possible causes for the pouch damage and has taken actions to prevent distribution of damaged pouches. Any future shipments to your facility will be free of this damage to the pouch.

Medtronic records show that your facility has received product lots that are within the scope of this advisory. Medtronic requests that you immediately remove any of these products with affected lot numbers (per attached list) remaining in your inventory. A Medtronic representative will assist you with expediting the return and free replacement of any unused catheters. If you have a scheduled Symplicity Renal Denervation case, please contact your Medtronic representative. For catheters that have already been used, patients should be managed in accordance with your standard patient management protocol. No additional patient follow up is recommended.

Medtronic is communicating this information to the appropriate regulatory agencies.

If you have any questions, please do not hesitate to contact your Medtronic sales representative or Medtronic Customer Service at 01923 212 213.

We appreciate your cooperation with this matter and apologize for the inconvenience that it may cause.

Yours sincerely,

A handwritten signature in black ink, appearing to read "L. Bridge".

Lezlie Bridge BSc. DMS
Regulatory Affairs Manager - UK & Ireland





Medtronic

URGENT FIELD SAFETY NOTICE

Symplicity® Catheters
Model RDN006

Product Recall

August 2012

Affected Lot Numbers:

0005823308	0006014706	0006109928
0005827214	0006029957	0006121305
0005827215	0006029959	0006121306
0005855604	0006029960	0006121333
0005855608	0006036734	0006121334
0005879459	0006036735	0006135710
0005879463	0006041217	0006135713
0005900259	0006041218	0006140932
0005900261	0006046663	0006140933
0005942612	0006046664	0006140934
0005942613	0006061962	0006140935
0005952728	0006061963	0006169423
0005952744	0006075389	0006169424
0005980388	0006075390	0006175901
0005981343	0006085707	0006175902
0005987994	0006097495	0006182376
0005987995	0006101679	0006182378
0006011307	0006103159	0006189770
0006011308	0006109907	0006189772
0006014704	0006109927	

