REPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
LE DIRECTEUR GÉNÉRAL

الجمهوريّة اللبنانيّة
وزارة الصحّة العامّة
المدير العام

رقم المحفوظات: ٣٧/ ٥٥
رقم الصادر: ١٢٧٦٩/١/١٤
بيروت، في: ٢٨ آب ٢٠١٢

## جانب نقيب المستشفيات الخاصة في لبنان

Therapy tissue ablation

**الموضوع:** إشعار بمتابعة جهاز طبي مغروس.

**الجهاز المعني 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 تفيد 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

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
وزارة الصحة العامة
المديرية العامة
قلم الديوان

وثيقة مصدقة للأصل
بيروت في ٣٠ آب ٢٠١٢
رئيس قسم امانة السر
عالية غصن

الجمهورية اللبنانية
رئاسة مجلس الوزراء
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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,

L J 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 | |