REPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
LE DIRECTEUR GÉNÉRAL

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ١/٢٨
رقم الصادر : ١٢٧٧٧/١/١٢
بيروت، في : ٢٨ آب ٢٠١٢

جانب شركة: Dima Health Care

surgical, diathermy electrode

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعني بالمتابعة:

- Surgical, diathermy electrode, DGP-I-IP RFA high-power single use grounding pad and Cool-tip RFA electrode kits.
  Trade Mark: Covidien LTD
  Local Representative: Dima Health Care

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 مما يؤدي الى إعادة اجراء العملية مرة أخرى، نطلب منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين 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
المديرية العامة
وزارة الصحة العامة
مكتب الديوان

وثيقة مصابقة للأصل
بيروت في ٣٠ آب ٢٠١٢
رئيس قسم امانة السر
عناية غصن

الجمهورية اللبنانية
وزارة الصحة العامة

REPUBLIQUE LIBANAISE
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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ١/٢٨
رقم الصادر: ١٢/١/١٣٧٧
بيروت، في: ٢٨ آب ٢٠١٢

جانب شركة: Mediline

Surgical, diathermy electrode

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعني بالمتابعة:

- Surgical, diathermy electrode, DGP-I-IP RFA high-power single use grounding pad and Cool-tip RFA electrode kits.
  Trade Mark: Covidien LTD
  Local Representative: Mediline

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

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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
عناية عصر

جمهورية لبنانية
وزارة الصحة العامة

COVIDIEN

REQUIRED ACTIONS:

1. **Immediately quarantine and discontinue use of the device.**

2. **Immediately advise all DGPHP RFA High-Power single use grounding pads and Cool-tip RF Electrode Kit users of this FSCA.** Please complete the attached Verification Form in its entirety. Send the completed form to the fax number or email address mentioned on the form. If you do not have any units from the affected lots in your inventory, simply return the Verification form indicating you have zero (0) units.

3. You will be contacted by our Customer Services representative to arrange return of affected products. You will receive credit for the returned affected products.

   We kindly request that you submit a new purchase order for new stock via the usual order channels.

   If you purchased product from a distributor please complete the Verification form (attached) and contact your Distributor directly. The completed form and all affected units must be returned through the Distributor.

4. We ask that you reply to Covidien ***WHETHER OR NOT*** you have affected product at your site. Your response is vital to our monitoring of the effectiveness of this FSCA. Please complete the attached form and return to Covidien.

   We know you share our interest in the primacy of patient safety and we sincerely apologize for any inconvenience this may cause. Thank you for your business and continued support.

   This action is being taken with the knowledge of [local Competent Authority].

   Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

   If you have any questions or concerns, please do not hesitate to contact your Covidien representative at [local contact details].

Sincerely,

Bryan Dannettell
Sr. Director, Quality Assurance EED Division

Attachment: Verification from

COVIDIEN

[Please insert date the form was sent]

URGENT MEDICAL DEVICE FSCA –

DGP-HP RFA High-Power single use grounding pads and Cool-tip™ RFA Electrode Kits

VERIFICATION FORM

Customer Contact Details	Covidien Contact Details
Hospital Name: **Covidien Account Number:**	**To:** [*please insert name Covidien commercial office*]
Collection Address: **Department:** Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	**Address:** [*please insert Covidien address*]
Telephone n°:	**Telephone n°:** [*please insert Covidien telephone number*]
Fax n°:	**Fax n°:** [*please insert Covidien fax number]*
E-mail:	**E-mail:** [*please insert contact e-mail address*]

Please list the quantity of affected product at your facility, if you have **no** stock, please indicate **'0'**.

Product code	Invoice or Despatch Note (if available)	Lot number	Qty

Information for the courier:

Number of parcels to collect: _____

Weight: ☐ < 45kg ☐ > 45kg

Name:
(please print) _____

Signature: _____

Date: _____

- Please fax this form to the fax number referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit for these products.
- Please don't send the goods back before having received the return documentation.
- **Even if you have no affected stock, please complete this form and return it to Covidien.**

COVIDIEN

URGENT FIELD SAFETY NOTICE

DGP-HP RFA High-Power single use grounding pads and Cool-tip™ RFA Electrode Kits (containing DGP-HP RFA High-Power single use grounding pads)

August 13, 2012

Attention: Risk Management Director and Materials Management

Please forward this communication to all surgeons, surgical personnel, interventional radiologists, hepatic internists, clinical engineering and any other potential users of the product.

Dear Valued Customer,

The purpose of this letter is to advise you that Covidien (formerly Valleylab, a division of Tyco Healthcare Group, L. P.) is performing a Field Safety Corrective Action (FSCA) on various production lots of the **DGP-HP RFA High-Power single use grounding pads and Cool-tip™ RFA Electrode Kits (containing DGP-HP RFA High-Power single use grounding pads).** The DGP-HP RFA High-Power single use grounding pads are intended for use as the dispersive electrode during radiofrequency lesioning procedures. The DGP-HP is specifically indicated for use with the Radionics Cool-tip™ RF System.

Serious injuries have occurred due to the failure of this product. We have received four reports of serious injuries involving patient burns at the DGP-HP pad site.

This FSCA is being conducted due to the potential for foil degradation on the DGP-HP RFA High-Power single use grounding pads. This foil degradation may result in an electrical disconnect and an undesirable thermal profile during use which may result in a patient burn at the pad site.

This FSCA is limited to the material codes and lot #'s identified and does ***NOT*** affect any other lots of Covidien devices.

Product Code	Lot Number Ranges*:		
ACT1020	168583	through	213736X
ACT1030	171281	through	215747X
ACT1507	168576	through	214355X
ACT1510	170882	through	214971X
ACT1520	168571	through	213013X
ACT1530	169419	through	220740
ACT2020	168854	through	213368X
ACT2030	168574	through	214434X
ACT2530	169684	through	214973
ACTC1025	171300	through	208194X

Product Code	Lot Number Ranges*:		
ACTC1525	168575	through	215632
ACTC2025	168853	through	213703X
SWCT1530	170383	through	213699X
SWCT15303	169683	through	213042X
SWCT1540	170384	through	215746X
SWCT2530	184240	through	205456
SWCT25303	177906	through	214357X
SWCT2540	191404	through	205455
DGPHP	162732	through	214867X

** Lot Numbers may contain a suffix "X"*