



رقم المحفوظات: ٤٥٨١
رقم الصادر: ٩٤٠٠١٣/١٢
بيروت، في:

١٢ فبراير ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بتابعة جهاز طبي

External defibrillator electrode pad, Medi-Trace Cadence
Defibrillation Electrode

الجهاز المعنى بالمتابعة:

- External defibrillator electrode pad, Medi Trace Cadence Defibrillation Electrode
- Trade Mark: Covidien
- Local Representative: Dima Health Care/ Mediline

بناء على التوصية الصادرة عن الشركة المصنعة التي تشير الى وجود خلل في استعمال الصنف

المذكور أعلاه، نرجو منكم تعميم هذه البشارة على جميع المستشفيات المعنية.

مرفق ربطا:

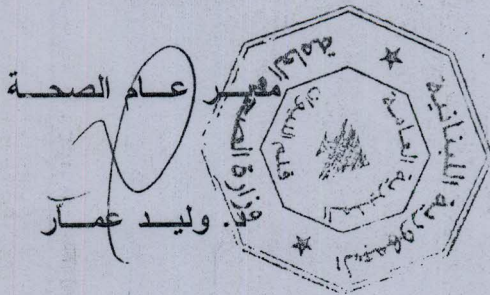
- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات





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URGENT FIELD SAFETY NOTICE

Medi-Trace™ Cadence Adult and Pediatric Radiotransparent Defibrillation Electrodes

April x, 2013

Dear Valued Customer,

We are informing you of a Field Safety Corrective Action (FSCA) regarding the Medi-Trace™ Cadence Adult and Pediatric RTS Defibrillation Electrodes. Please forward this communication to all Emergency Departments / Personnel, EP labs, Cath labs and any other potential users of the product.

We have received customer reports of Arcing/Sparking on the defibrillation electrode lead wire. We have become aware that the vendor who supplies Covidien with the wire/connector subassembly experienced equipment damage due to misalignment from tooling installed in August 2012. This could result in arcing, sparking, or thermal damage to the lead wire, which could render the device incapable of delivering the appropriate energy or shock to the patient.

Although we have received no reports of patient injury, we have determined that all Medi-Trace™ Cadence Adult and Pediatric RTS Defibrillation Electrodes from the lots listed below should be returned. We are requesting your assistance in conducting this activity. Please review your inventory and segregate any product with the affected lot numbers and return affected product according to the below directions.

The FSCA applies to the following 12 lot numbers:

| Product ID | Description | Lot # | |
|------------|---|---------|---------|
| 22550R | Medi-Trace™ Cadence Adult Radiotransparent Defibrillation Electrode | 226543X | 235641X |
| | | 230814X | 300446X |
| | | 232182X | 305320X |
| | | 234245X | |
| 22550P | Medi-Trace™ Cadence Pediatric Radiotransparent Defibrillation Electrode | 228651 | 303928X |
| | | 232146 | |
| | | 235646X | |
| | | 301833X | |

Please complete the attached Verification Form in its entirety. Fax the completed Form to the fax number or email address stated on the form. If you do not have any units in your inventory, simply return the Verification Form indicating that you have zero (0) units. You will be contacted by Customer Services to arrange return of affected products. You will be receiving credit for returned products.

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

Please report any issues with the Medi-Trace™ Cadence Adult and/or Pediatric Radiotransparent Defibrillation Electrodes to your Covidien representative at [add local contact number].

This FSCA is being conducted with the knowledge of the [add local Competent Authority]. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

Michael P. Spears
Vice President, Quality Assurance and Regulatory Affairs
Medical Supplies