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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨١/٢٥
رقم الصادر: ١٣/٧٢٠٢٥
بيروت، في: ١٢ حزيران ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Pulsed Dose Rate, Segmented Cylinder Applicator Set

الجهاز المعني بالمتابعة:

- Pulsed Dose Rate, Segmented Cylinder Applicator Set
- Trade Mark: Varian Medical Systems
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
الذي يشير الى وجود خلل في عمل الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:
- التقرير الصادر عن وكالة ال FDA

يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
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Medical & Radiation Emitting Device Recalls

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Class 2 Recall
Segmented Cylinder Applicator Set

See Related Information 20

Date Posted	May 15, 2013
Recall Number	Z-1324-2013
Product	Segmented Cylinder Applicator Set, Model # GM11004150, when used for Pulsed Dose Rate (PDR) Product Usage: Usage: Used during pulsed dose rate brachytherapy to treat vaginal and rectal cancer.
Code Information	Serial numbers H640383, H640277, H640384, H640788, H640D126, H640385, H640372, H640303, H640387
Recalling Firm/ Manufacturer	Varian Medical Systems, Inc. 700 Harris St Ste 109 Charlottesville, Virginia 22903-4584
For Additional Information Contact	Mark Kattman 434-977-8495
Reason for Recall	Segmented cylinder applicator set may slip during treatment, causing the delivery of radiation to areas outside the target.
Action	Varian Medical Systems, Inc. notified customers of the recall with 'Urgent Medical Device Correction Urgent Field Safety Notice," dated 4/11/13, and delivered by mail to customers. The notice identified the product, problem, and instructions for the customers. Varian Medical Systems, Inc. informed customers of the possible malfunction of the GM11004150 Segmented Cylinder Applicator Set for pulsed dose rate brachytherapy treatment, with codes H640383, H640277, H640384, H640788, H640D126, H640385, H640372, H640303, H640387. The notice instructed customers to cease use of the Segmented Cylinder Applicator Set and return the devices along with a completed proof of notification form (included with the recall notice) to the recalling firm.
Quantity in Commerce	21 devices
Distribution	Worldwide Distribution in the countries of: Belgium, France, Martinique, Slovenia, Sweden, and the United Kingdom.

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8. ../cfRL/rl.cfm
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