الموضوع: إشعار ب配套设施 الخاصة في لبنان

Pulsed Dose Rate, Segmented Cylinder Applicator Set

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

FDA

بناءً على التقرير الصادر عن وكالةFDA الذي يشير إلى وجود خلل في عمل الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربيطاً:

FDA التقرير الصادر عن وكالة FDA

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- المحفوظات

د. وليد عبكر
Radiation Emitting Device Recalls

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New Search

Class 2 Recall
Segmented Cylinder Applicator Set

Date Posted
May 15, 2013

Recall Number
Z-1324-2013

Product
Segmented Cylinder Applicator Set, Model # GM1004150, 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.
720 Harris St Ste 105
Charlottesville, Virginia 22903-4584

For Additional Information Contact
Mark Kattman
434-977-8609

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 GM1004150 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.

Links on this page:
domain
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ./cPHR/pm.cfm
8. ./cURL/c.cfm
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