RÉPUBLIQUE LIBANAISE
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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٢٥
رقم الصادر: ١٣/١/١٤٠٧٩
بيروت، في: ٢٤ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Bipolar Coagulator, use in surgery

الجهاز المعني بالمتابعة:

- Bipolar Coagulator, use in surgery
- Trade Mark: Aesculap
- Local Representative:

بناءً على التقرير الصادر عن وكالة FDA، والذي يشير الى وجود خلل في استعمال الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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Class 2 Recall Aesculap(R) Bipolar Coagulator/Foot Pedal

See Related Information [20]

Date Posted	February 26, 2013
Recall Number	Z-0887-2013
Product	Aesculap Bipolar Generator Foot Pedal, Catalog No. GK226, for electrosurgical cutting and coagulation.
Code Information	Manufacture date on the label on the bottom of the foot pedal - any product with manufactured dates between 45/10 and 31/12
Recalling Firm/ Manufacturer	Aesculap, Inc. 3773 Corporate Pkwy Center Valley, Pennsylvania 18034-8217
For Additional Information Contact	Kathy A. Racosky 800-258-1946 Ext. 5067
Reason for Recall	The bipolar energy did not stop after release of the foot pedal.
Action	Aesculap AG sent an Important Recall Notification letter dated January 21, 2013 to all affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to examine inventory and return for a replacement product or credit. The letter included an inventory sheet to be completed by the customer and returned to the recalling firm. For question call 610-984-9265 or 610-984-9291.
Quantity in Commerce	59
Distribution	USA Nationwide Distribution including the states of: AR, CA, FL, IN, IA, KS, MD, MN, MO, OR, TN, TX, VA and WA.

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