RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨١/٥٥
رقم الصادر: ١٥٦٨٤/١/٣
بيروت، في: ٩ أيار ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Intraoperative cortical stimulation, Ojemann Cortical Stimulator

الجهاز المعني بالمتابعة:

- Intraoperative cortical stimulation, Ojemann Cortical Stimulator
- Trade Mark: Integra LifeSciences Corporation
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

والذي يشير الى وجود خلل في عمل الصنف المذكور اعلاه مما قد يؤثر على سلامة المريض، 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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U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

Class 2 Recall
Integra Life Sciences Ojemann Cortical Stimulator

See Related Information 20

Date Posted	April 01, 2013
Recall Number	Z-1030-2013
Product	Integra Ojemann Cortical Stimulator; Product / Catalogue No: OCS2. Intended for intraoperative cortical stimulation mapping procedures.
Code Information	Serial Number Range: 1010 through 1380
Recalling Firm/ Manufacturer	Integra Burlington MA, Inc. 22 Terry Ave Burlington, Massachusetts 01803-2516
For Additional Information Contact	Same 781-272-1233
Reason for Recall	If the headphone jack is in use during a surgical procedure with the OCS2 and a non-intended voltage (such as static electricity) comes in contact with the outer case of the unit, that voltage could be transmitted to the patient and could be a potential source of injury.
Action	Integra initiated a voluntary recall on March 18, 2013 by providing written notification to consignees either by traceable courier service or traceable emails regarding the correction that Integra records indicate have an OCS2 since it was introduced to the market in 2007. The consignee notification: Advised of the nature of the issue and to immediately stop using the headphone jack while using the OCS2. Requested identification by S/N any OCS2's they have, and complete / return the Acknowledgment Return Form. Advised that Integra will contact the consignee to schedule a time / date to correct the OCS2's they have identified. Questions, contact service hotline at 1-888-772-7378.
Quantity in Commerce	371 units
Distribution	Worldwide Distribution-USA (nationwide) and the countries of Austria, Belgium, Czech Republic, Belgium, Denmark, Spain, Great Britain, Hungary, Ireland, Italy, Netherlands, Poland, Morocco, Netherlands, Poland, Portugal, Saudia Arabia, Sweden, Turkey, and South Africa.

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