REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
THE DIRECTOR GENERAL

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٢٠
رقم الصادر: ١٣/١/١٤٤٦٢
بيروت، في: ٢٦ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Bearing Sleeve with removable Bur Guard

الجهاز المعني بالمتابعة:

- Bearing Sleeve with removable Bur Guard
- Trade Mark: The Anspach Effort, Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA الذي يحذر فيه من استعمال الصنف المذكور أعلاه نظراً لاحتمال وجود مضاعفات على المريض اثناء الاستعمال ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

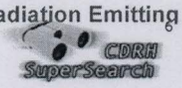
- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

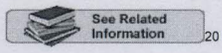
مدير عام الصحة
د. وليد عمار

Medical & Radiation Emitting Device Recalls



New Search Back to Search Results

Class 2 Recall
Bearing Sleeve with Removable Bur Guard



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Date Posted	February 04, 2013
Recall Number	Z-0783-2013
Product	Anspach Effort, Inc., 98-0061 MA-15C Bearing Sleeve with Removable Bur Guard. A reusable device used with dissection tools; designed for Transphenoidal and Skull base procedures.
Code Information	Lot number: 2000930
Recalling Firm/ Manufacturer	The Anspach Effort, Inc. 4500 Riverside Drive Palm Beach Gardens, Florida 33410-4235
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Jessica Smith 561-627-1080
Reason for Recall	Contact between the bur and bur guard could generate metal fragments that may or may not be visible to the surgeon and can potentially remain in the surgical site. The materials used to fabricate the bur guard are not traceable, design validation did not effectively evaluate adequate protection of adjacent tissue and inspection results for each of these bur guards were not documented.
Action	The firm, Anspach Effort, Inc. sent an "URGENT: Medical Device Removal" letter dated November 7, 2012, to its customer. The letter identified the product, problem and actions to be taken. The customer was instructed to do the following: 1) Screen their inventory and remove and return all products immediately. 2) Complete and return the attached Customer Reply Form via fax or email to the address provided on the form. Should the customer have any questions, please contact Anspach Product Support at (800) 327-6887.
Quantity in Commerce	8 devices
Distribution	Distributed in the state of Massachusetts

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