RÉPUBLIQUE LIBANAISE
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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨١٧٥
رقم الصادر: ١٤٤٠/١٢/٧
بيروت، في: ١٢ مزيران ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Biological, Collagen, Absorbable, Many products manufactured by Integra LifeSciences Corporation

الجهاز المعني بالمتابعة:

- Biological, Collagen, Absorbable, Many products manufactured by Integra LifeSciences Corporation
- Trade Mark: Integra LifeSciences Corporation
- Local Representative: Asmar Medical

بناء على التقرير الصادر عن وكالة ال FDA

الذي يشير الى وجود خلل في عملية التصنيع 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
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
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Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

See Related Information[20]

Class 2 Recall
Layershield® Adhesion Barrier Matrix

Date Posted	May 10, 2013
Recall Number	Z-1300-2013
Product	Layershield Adhesion Barrier Matrix Layershield Adhesion Barrier Matrix is an absorbable implant for use as an adhesion barrier for the reduction of peridural fibrosis.
Code Information	1125812 1125816 1126021
Recalling Firm/ Manufacturer	Integra LifeSciences Corporation 105 Morgan Ln Plainsboro, New Jersey 08536-3339
Reason for Recall	Due to the process deviation, product lots in question may have been released with higher levels of pyrogens than permitted by the specifications for the products.
Action	The firm, Integra, sent an "URGENT: MEDICAL DEVICE RECALL" letter dated April 9, 2013, to all US, Canada, and non-EU Integra consignees/customers. The letter described the product, problem and actions to be taken. The customers were instructed to verify if they have any lots of the listed product, if so, STOP using that product; remove the product from service; and promptly complete and return the PRODUCT RECALL RETURN ACKNOWLEDGMENT FORM via Email: FCA@integralife.com or FAX to : 1-609-275-9445. Customer Service department will contact you to return and replace the product. "However, if you have already implanted or used collagen sponge products affected by this recall, we recommend you monitor the patient for a fever in the immediate postoperative period according to the standard hospital or clinician protocol." For assistance or any other questions that you may have, please contact Customer Service at 1-855-532-1723.
Quantity in Commerce	215 boxes
Distribution	Worldwide distribution: USA (nationwide) including Puerto Rico and countries of: Arab Emirates, Argentina, Belgium, Brasil, Canada, Chile, China, Costa Rica, Denmark, Egypt, Spain, France, Great Britain, Italy, Japan, Peru, Singapore, Thailand, and South Africa.

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