جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

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

الجهاز المعنى 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 إلى وجود خلل في عملية التصنيع مما قد مؤثر على سلامة المريض، نرجو منكم تعريض هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التقرير الصادر عن وكالة ال FDA

بلاغ:

- دائرة البرامج والمشاريع المستشفيات الحكومية المحفوظات
Layershield® Adhesion Barrier Matrix is an absorbable implant to be used as an adhesion barrier for the reduction of periurethral fibrosis.

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 product.

The firm, Integra, sent an "URGENT: MEDICAL DEVICE RECALL" letter dated April 9, 2013, to all US, Canada, and non-EU Integra 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 products, stop using the product, and promptly complete and return the PRODUCT RECALL RETURN ACKNOWLEDGMENT FORM via Email: FCA@IntegraLife.com or FAX to: 1-800-275-9445. 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.

Worldwide distribution: USA (nationwide) including Puerto Rico and countries of: Arab Emirates, Argentina, Belgium, Brazil, Canada, Chile, China, Costa Rica, Denmark, Egypt, Spain, France, Great Britain, Italy, Japan, Peru, Singapore, Thailand, and South Africa.