



رقم المحفوظات: ٤٥ / ٨١
رقم الصادر: ١٣ / ١ / ٢٥٧٩١
بيروت، في:
٢ - آب - ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Suture, Digitex 2-0 Polydioxanone (PDO) suture

الجهاز المعنى بالمتابعة:

- Suture, Digitex 2-0 Polydioxanone (PDO) suture
- Trade Mark: Coloplast A/S
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خطأ في تاريخ الصلاحية مما 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



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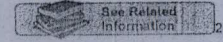


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Class 2 Recall
Digitex 2-0 Polydioxanone (PDO)
suture



Date Posted	June 05, 2013
Recall Number	Z-1486-2013
Product	Digitex Absorbable Polydioxanone Suture, Size 2-0. Catalog Number / Code of product: 52031, 5203101400. The Digitex Delivery Device is a sterile, disposable device intended to deliver a suture to the operative site. The device assists in suturing by passing a needle through the tissue to capture the suture, and suture ligation and know-typing by holding the suture.
Code Information	Lots 3390331, 3390339, 3390490.
Recalling Firm/Manufacturer	Coloplast Manufacturing US, LLC 1601 W River Rd Minneapolis, Minnesota 55411-3431
Reason for Recall	Coloplast is conducting a recall on three lots of Digitex Absorbable Polydioxanone Suture, Size 2-0 because it is mislabeled with a three year expiration date.
Action	The firm, Coloplast, sent a letter dated May 8, 2013 to its customers. The letter described the problem, the product and actions to be taken. The customers will be contacted by Coloplast Customer Service with instructions for the handling and return of any unused product. If you have any additional questions, the dedicated Customer Service number regarding this effort is 800-258-3476.
Quantity in Commerce	772 units
Distribution	US Distribution to: KY, MI, OH, PR, TX, and VA.

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