



رقم المحفوظات: ٧٧/٢٥
رقم الصادر: ١٣/١/٢٨٦١٩
بيروت، في: ٢٠ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Reinforced Wound Closure

الجهاز المعنى بالمتابعة:

- Reinforced Wound Closure
- Trade Mark: Aspen Surgical Products, Inc.
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA ،

الذي يشير الى وجود خلل في عملية تعقيم الجهاز المذكور أعلاه ، 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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Medical & Radiation Emitting Device Recalls

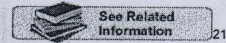


510(k)⁷ | Registration & Listing⁸ | Adverse Events⁹ | Recalls¹⁰ | PMA¹¹ | Classification¹² | Standards¹³ | Inspections¹⁴ | CFR Title 21¹⁵ | Radiation-Emitting Products¹⁶ | X-Ray Assembler¹⁷ | Medsun Reports¹⁸ | CLIA¹⁹ | TPLC²⁰

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Class 2 Recall
Wound Closure Strips



Date Posted	August 20, 2013
Recall Number	Z-1988-2013
Product	Distributed in USA: Product Number: 40-2894: Reinforced Wound Closure, Latex Free Sterile EO Rx, 1/4" X 4", 6 mm X100 mm, (2 Cards/pouch, 1,000 Pouches/box); Distributed in Europe: " Product Number: 39-0058: Medicare Reinforced Wound Closure Strips 1/4" X 4", Sterile, Box 1000 pouches 5 strips /pouch, Pouch , 5 strips 6 mm X100 mm Sterile EO Product Number: 40-2893: Wound Closure Strips , Sterile (1,000pouches/box) Rx; Pouch Label: Wound Closure Strips 6 mm X100 mm, 1/4" X 4", Rx Product Usage: intended for skin closure and closure support for sutures and staples
Code Information	Product 40-2894: Lot Numbers/Expiration Date Lot Numbers/Expiration 2690-090730 2014-07 2690-111128 2016-11 2690-091207 2014-12 2690-111205 2016-12 2690-100309 2015-03 2690-29661 2017-01 2690-100407 2015-04 2690-29775 2017-01 2690-100429 2015-04 2690-120307 2017-03 2690-100505 2015-05 2690-120410 2017-03 2690-100603 2015-06 2690-120425 2017-04 2690-100607 2015-06 2690-120517 2017-05 2690-100615 2015-06 2690-120803 2017-08 2690-100617 2015-06 2690-120822 2017-08 2690-100709 2015-07 2690-120917 2017-09 2690-100728 2015-07 2690-121019 2017-10 2690-101001 2015-10 2690-121106 2017-10 2690-101101 2015-11 2690-121105 2017-11 2690-101117 2015-11 2690-121128 2017-11 2690-101221 2015-12 2690-130107 2018-01 2690-110121 2016-01 2690-130103 2018-01 2690-110201 2016-02 2690-130109 2018-01 2690-110217 2016-02 2690-130215 2018-02 2690-110223 2016-02 2690-130307 2018-03 2690-110310 2016-03 2690-130213 2018-02 2690-110328 2016-03 2690-130306 2018-03 2690-110415 2016-04 2690-130403 2018-04 2690-110426 2016-04 2690-130409 2018-04 2690-110511 2016-02 2690-130415 2018-04 2690-120804 2017-08 " Product 39-0058 (outside USA): Lot Numbers/ Expiration Date 11305 2016-05 11731 2017-03 11974 2017-08 12353 2018-04 " Product 40-2893 (outside USA): Lot Numbers/ Expiration Date 10425 2014-11 10504 2014-07 10727 2015-02 11178 2015-10 11179 2015-12 11260 2016-01 11261 2016-02 11558 2016-07
Recalling Firm/ Manufacturer	Aspen Surgical Products, Inc. 6945 Southbelt Dr Se Caledonia, Michigan 49316-7664
For Additional Information Contact	Kelli Jonas, 888-364-7004 Ext. 177
Reason for Recall	Aspen Surgical is recalling Wound Closures because firm could not confirm sterility, after FDA sampling indicated the product may not be sterile. Using the recalled product could lead to infection which may require further treatment including the use of antibiotics. There have been no reports of injuries or illnesses as of 7/18/2013.
Action	Aspen sent an Urgent Medical Device Recall letter dated July 18, 2013 via certified mail to all customers with directions to forward the notification and provide Aspen with sub-account information. Aspen has given the customers the option to either 1.) Return the product 2.) Destroy the product with a Certificate of Destruction to be provided to Aspen. Any returned product to Aspen will be put on MRB and dispositioned by Quality. Questions or concerns should be addresses to Kelli Jona Directo of QA / RA at 888-364-7004 ext 177 jonask@aspensurgical.com or Michelle Pulaski, Quality System and Compliance Manager 888-364-7004 ext 143 pulaskim@aspensurgical.com 8-5 EST M-F.
Quantity in Commerce	3286 boxes (6,353,000)
Distribution	Worldwide Distribution - US Nationwide in the state of Florida and in the countries of , Netherlands, and Reditch Worcestershire England

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