



رقم المحفوظات: ٤٨/٢٥
رقم الصادر: ١٢/١/٢٥٢١٢
بيروت، في: ٢٠ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Surgical instruments, implant impactor, Dorado Straight Impactor

الجهاز المعنى بالمتابعة:

- Surgical instruments, implant impactor, Dorado Straight Impactor
- Trade Mark: SpineFrontier Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف المذكور
أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
وزير
د. وليد عمار

[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Medical & Radiation Emitting Device Recalls

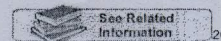


[510\(k\)](#)⁷ [Registration & Listing](#)⁸ [Adverse Events](#)⁹ [Recalls](#)¹⁰ [PMA](#)¹¹ [Classification](#)¹² [Standards](#)¹³
[CFR Title 21](#)¹⁴ [Radiation-Emitting Products](#)¹⁵ [X-Ray Assembler](#)¹⁶ [Medsun Reports](#)¹⁷ [CLIA](#)¹⁸ [TPLC](#)¹⁹

[New Search](#)

[Back to Search Results](#)

**Class 2 Recall
Dorado Straight Impactor**



Date Posted	June 05, 2013
Recall Number	Z-1482-2013
Product	Straight Impactor - Dorado IBC, Part Number: SI02140. The device is used to position implants after they have been inserted into the disc space during implantation of intervertebral body fusion devices.
Code Information	Lot number: 20856
Recalling Firm/ Manufacturer	SpineFrontier, Inc. 500 Cummings Ctr Ste 3500 Beverly, Massachusetts 01915-6516
For Additional Information Contact	Nicole Baginski 978-232-3990
Reason for Recall	During two separate occasions an impactor plate on the handle broke off while being struck by a mallet.
Action	Firm states they notified consignees of recall between 5/10/08 and 5/22/2008. Zero product is currently in distribution.
Quantity in Commerce	10
Distribution	MA, TX, CO, Jamaica.

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. <..cfPMN/pmn.cfm>
8. <..cfRL/rl.cfm>
9. <..cfMAUDE/TextSearch.cfm>
10. <..cfRES/res.cfm>
11. <..cfPMA/pma.cfm>
12. <..cfPCD/classification.cfm>
13. <..cfStandards/search.cfm>
14. <..cfCFR/CFRSearch.cfm>
15. ..cfPCD_RH/classification.cfm
16. <..cfAssem/assembler.cfm>
17. <..Medsun/searchReportText.cfm>
18. <..cfClia/Search.cfm>
19. <..cfTPLC/tplc.cfm>
20. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=medical%20device%20recalls%20&item1_url=www.fda.gov/medicaldevices/safety/recalls/corrections/removals/listofrecalls/default.htm&item2_text=fda%20enforcement%20report%20index&item2_url=www.fda.gov/safety/recalls/enforcementreports/default.htm

Page Last Updated: 06/28/2013

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).
[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No Fear Act](#) [Site Map](#) [Transparency](#) [Website Policies](#)

U.S. Food and Drug Administration
 10903 New Hampshire Avenue
 Silver Spring, MD 20993