



رقم المحفوظات: ٩/٢٥
رقم الصادر: ١٣/١٧.٢٤
بيروت، في: ٢٠ أيار ٢٠١٢

جانب نقيب الاطباء في الشمال/طرابلس

الموضوع: إشعار بمتابعة جهاز طبي

Nails, Bone, Synthes Flexible grip

الجهاز المعنى بالمتابعة:

- Nails, Bone, Synthes Flexible grip
- Trade Mark: Synthes Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

الذي يشير الى وجود خلل في عملية تنظيف وتعقيم الجهاز المذكور أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين.

مرفق ربطاً:

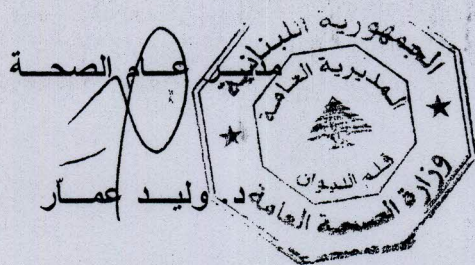
- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات



[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 21¹⁴ | [Radiation-Emitting Products](#)¹⁵ | [X-Ray Assembler](#)¹⁶ | [Medsun Reports](#)¹⁷ | [CLIA](#)¹⁸ | [TPLC](#)¹⁹

[New Search](#)

[Back to Search Results](#)

Class 2 Recall Synthes Flexible Grip



Date Posted	April 05, 2013
Recall Number	Z-1062-2013
Product	Flexible Grip which is part of the Synthes Universal Nail System. Indicated for the conventional (non-locking) technique of treating stable diaphyseal fractures.
Code Information	Part number 355.28, all lot numbers
Recalling Firm/ Manufacturer	Synthes USA HQ, Inc. 1302 Wrights Ln E West Chester, Pennsylvania 19380-3417
Reason for Recall	Synthes is initiating a voluntary recall of the Flexible Grip (Part number 355.28) which is part of the Universal Nail System, due to the potential lack of the ability to thoroughly clean the instrument.
Action	Synthes sent an "URGENT NOTICE: MEDICAL DEVICE RECALL" dated January 11, 2013 to all affected customers. The letter identified the product, problem, and actions to be taken by the customers. The letter requested consignees examine inventory, remove the recalled products from use and return them to Synthes. If you have any questions, contact the firm at 610-719-5450.
Quantity in Commerce	328
Distribution	Nationwide Distribution including the states of AZ, CA, CO, FL, IA, ID, GA, IL, IN, KY, LA, MA, MD, MI, MN, MO, MS, NC, NH, NJ, NV, NY, OH, PA, RI, TN, TX, UT, VT, WA, WI, and WV.

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
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](..cfPMN/pmn.cfm)
8. [../cfRRL/rl.cfm](..cfRRL/rl.cfm)
9. [../cfMAUDE/TextSearch.cfm](..cfMAUDE/TextSearch.cfm)
10. [../cfRES/res.cfm](..cfRES/res.cfm)
11. [../cfPMA/pma.cfm](..cfPMA/pma.cfm)
12. [../cfPCD/classification.cfm](..cfPCD/classification.cfm)
13. [../cfStandards/search.cfm](..cfStandards/search.cfm)
14. [../cfCFR/CFRSearch.cfm](..cfCFR/CFRSearch.cfm)
15. [../cfPCD_RH/classification.cfm](..cfPCD_RH/classification.cfm)
16. [../cfAssem/assembler.cfm](..cfAssem/assembler.cfm)
17. [../Medsun/searchReportText.cfm](..Medsun/searchReportText.cfm)
18. [../cfCla/Search.cfm](..cfCla/Search.cfm)
19. [../cfTPLC/tplc.cfm](..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: 05/13/2013

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

Ph. 1-888-INFO-FDA (1-888-463-6332)