



رقم المحفوظات: ٤٥ / ١٣١  
رقم الصادر: ١٣١/١٥٦٨٧  
بيروت، في: ٩ أيار ٢٠١٢

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي مغروس  
OsteoSelect DBM Putty, Orthopedic bone filler

الجهاز المعني بالمتابعة:

- OsteoSelect DBM Putty, Orthopedic bone filler
- Trade Mark: Bacterin International, Inc.
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA والذي يشير الى سحب هذا الصنف من الأسواق وعدم استعماله لعدم التأكد من جودته، نرجو منكم متابعة هذا الموضوع مع الاطباء المعنيين.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

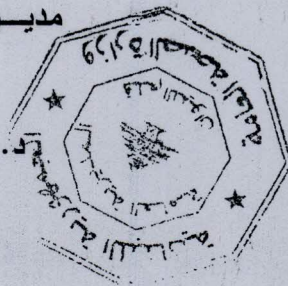
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- المستشفيات الحكومية

- المحفوظات

مدير عام الصحة

وليد عمار



U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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**Class 2 Recall  
OsteoSelect**

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|   |  |
|---|--|
| <b>Date Posted</b>                            | April 17, 2013   |
| <b>Recall Number</b>                          | Z-1138-2013  |
| <b>Product</b>                                | OsteoSelect DBM Putty Product Usage: Orthopedic bone filler  |
| <b>Code Information</b>                       | B100164 and B110115  |
| <b>Recalling Firm/<br/>Manufacturer</b>       | Bacterin International, Inc.<br>600 Cruiser Ln<br>Belgrade, Montana 59714-9719   |
| <b>For Additional<br/>Information Contact</b> | Casey Ming, CTBS<br>406-388-0480   |
| <b>Reason for<br/>Recall</b>                  | The firm's retesting procedure was not validated.  |
| <b>Action</b>                                 | Bacterin sent a Voluntary Product Recall Notification letter via e-mail to all affected customers. The letter identified the affected product, problem and actions to be taken. Customers are being asked to return any remaining product by obtaining a Return Authorization number from them. Bacterin is also asking customers to return the verification form mailed with the recall letter regardless of whether or not they had any product on hand. For questions contact Bacterin sales representative or Bacterin Customer Service. |
| <b>Quantity in Commerce</b>                   | 165  |
| <b>Distribution</b>                           | USA Nationwide Distribution  |

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16. <..cfAssem/assembler.cfm>
17. <..Medsun/searchReportText.cfm>
18. <..cfCla/Search.cfm>
19. <..cfTPLC/tpic.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%](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%)