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المدير العام

رقم المحفوظات: ٢٩/ ٢٠٠٥
رقم الصادر : ١٣/١/١٧٠٢٨
بيروت، في :
٢٠ أيار ٢٠١٣

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي
APLIF Implants and Instruments, The Eminent Spine Interbody Fusion System

الجهاز المعني بالمتابعة:

- APLIF Implants and Instruments, The Eminent Spine Interbody Fusion System
- Trade Mark: Spinal Solutions LLC
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
الذي يشير الى نقص في الفحوصات التي تثبت فعالية الصنف الوارد أعلاه من ناحية الجودة أو عملية التعقيم، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين.

مرفق ربطاً:
- التقرير الصادر عن وكالة ال FDA

يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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وزير الصحة العامة
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Class 2 Recall
APLIF Implants and Instruments

Date Posted	April 22, 2013
Recall Number	Z-1157-2013
Product	APLIF Implants and Instruments, Part Numbers: 184008-10 Anterior Psoas Lumbar 18 x 40 x 08mm - 10degree 184010-10 Anterior Psoas Lumbar 18 x 40 x 10mm - 10degree 184012-10 Anterior Psoas Lumbar 18 x 40 x 12mm - 10degree 184014-10 Anterior Psoas Lumbar 18 x 40 x 14mm - 10degree 184016-10 Anterior Psoas Lumbar 18 x 40 x 16mm - 10degree 184008-00 Anterior Psoas Lumbar 18 x 40 x 08mm - 00degree 184010-00 Anterior Psoas Lumbar 18 x 40 x 10mm - 00degree 184012-00 Anterior Psoas Lumbar 18 x 40 x 12mm - 00degree 184014-00 Anterior Psoas Lumbar 18 x 40 x 14mm - 00degree 184016-00 Anterior Psoas Lumbar 18 x 40 x 16mm - 00degree 184510-08 Anterior Psoas Lumbar 18 x 45 x 08mm - 10degree 184510-10 Anterior Psoas Lumbar 18 x 45 x 10mm - 10degree 184512-10 Anterior Psoas Lumbar 18 x 45 x 12mm - 10degree 184514-10 Anterior Psoas Lumbar 18 x 45 x 14mm - 10degree 184516-10 Anterior Psoas Lumbar 18 x 45 x 16mm - 10degree 184510-00 Anterior Psoas Lumbar 18 x 45 x 10mm - 00degree 184512-00 Anterior Psoas Lumbar 18 x 45 x 12mm - 00degree 184514-00 Anterior Psoas Lumbar 18 x 45 x 14mm - 00degree 184516-00 Anterior Psoas Lumbar 18 x 45 x 16mm - 00degree 185008-10 Anterior Psoas Lumbar 18 x 50 x 08mm - 10degree 185010-10 Anterior Psoas Lumbar 18 x 50 x 10mm - 10degree 185012-10 Anterior Psoas Lumbar 18 x 50 x 12mm - 10degree 185014-10 Anterior Psoas Lumbar 18 x 50 x 14mm - 10degree 185016-10 Anterior Psoas Lumbar 18 x 50 x 16mm - 10degree 185008-00 Anterior Psoas Lumbar 18 x 50 x 08mm - 00degree 185010-00 Anterior Psoas Lumbar 18 x 50 x 10mm - 00degree 185012-00 Anterior Psoas Lumbar 18 x 50 x 12mm - 00degree 185014-00 Anterior Psoas Lumbar 18 x 50 x 14mm - 00degree 185016-00 Anterior Psoas Lumbar 18 x 50 x 16mm - 00degree 185508-10 Anterior Psoas Lumbar 18 x 55 x 08mm - 10degree 185510-10 Anterior Psoas Lumbar 18 x 55 x 10mm - 10degree 185512-10 Anterior Psoas Lumbar 18 x 55 x 12mm - 10degree 185514-10 Anterior Psoas Lumbar 18 x 55 x 14mm - 10degree 185516-10 Anterior Psoas Lumbar 18 x 55 x 16mm - 10degree 185508-00 Anterior Psoas Lumbar 18 x 55 x 08mm - 00degree 185510-00 Anterior Psoas Lumbar 18 x 55 x 10mm - 00degree 185512-00 Anterior Psoas Lumbar 18 x 55 x 12mm - 00degree 185514-00 Anterior Psoas Lumbar 18 x 55 x 14mm - 00degree 185516-00 Anterior Psoas Lumbar 18 x 55 x 16mm - 00degree The Eminent Spine Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment.
Code Information	All lots are subject to this recall.
Recalling Firm/ Manufacturer	Spinal Solutions, LLC 26157 Jefferson Ave Murrieta, California 92562-9561
Reason for Recall	Spinal Solutions is recalling the APLIF system because it is not supported by adequate testing and documentation to demonstrate that it meets performance or safety standards. These inadequacies might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization.
Action	Spinal Solutions LLC sent an Urgent Medical Device Recall letter dated April 12, 2013, to all affected customers. The letter informed the customers of the problem identified and the actions to be taken. Customers were instructed to discontinue use of the affected product and return to the firm. Customers were also instructed to complete the bottom of the form and to return it by fax to (858) 764-9739. For questions regarding this recall call 951-304-9001.
Quantity in Commerce	220 units
Distribution	Nationwide Distribution including NV, WI, MD,and CA.

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