



رقم المحفوظات: ٢٠١٣
رقم الصادر: ١٣/١/١٤٤٧٨
بيروت، في: ٢٢ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Cervical Screws, 3.75mm x 12mm, Spine Anterior Cervical

الجهاز المعنى بالمتابعة:

- Cervical Screws, 3.75mm x 12mm, Spine Anterior Cervical
- Trade Mark: Genesys Orthopedic Systems
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

الذي يشير الى احتمال حدوث مضاعفات جراء استعمال الصنف المذكور اعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

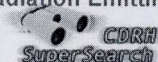
يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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Medical & Radiation Emitting Device Recalls

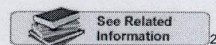


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**Class 2 Recall
Fixed Cervical Screws**



Date Posted	March 08, 2013
Recall Number	Z-0921-2013
Product	3.75mm x 12mm Fixed Cervical Screws. Components of the Genesys Spine Anterior Cervical Plate System Product Usage: is intended for anterior screw fixation to the cervical spine.
Code Information	Part Number: GCSF37512 and Lot Number: 0243
Recalling Firm/ Manufacturer	Genesys Orthopedic Systems, LLC 1250 S Capital Of Texas Hwy Bldg #3, Suite 600 Austin, Texas 78746-6446
For Additional Information Contact	Joshua Kaufman 512-381-7070
Reason for Recall	Manufacturing residue may be present on the cervical screws. Use of this product may result in patient infection, delayed fusion or non-fusion (pseudarthrosis), inflammatory response, or revision surgery.
Action	Genesys Orthopedic Systems, LLC sent a Recall Notification letter dated February 20, 2013 to all affected customers. The letter identified the affected product, problem and necessary actions to be taken. Customers were instructed to immediately return the affected product to the Genesys Spine office and complete and return the enclosed Response Form as soon as possible. For questions call 512-381-7070.
Quantity in Commerce	9 cervical screws
Distribution	USA Nationwide Distribution including the states of: CA and TX.

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