REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/ ٢٥
رقم الصادر: ١٢/١/٢٥٣٦
بيروت، في: ٣ كانون الأول ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Distal Femoral Augment with Screw, SC2316

الجهاز المعني بالمتابعة:

- Distal Femoral Augment with Screw, SC2316
- Trade Mark: Stelkast Co
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

والذي يشير الى وجود خلل في عملية توضيب الصنف المذكور أعلاه مما قد يؤثر على فعالية التعقيم، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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Class 2 Recall
SC2316, Distal Femoral Augment with Screw

See Related Information[21]

Date Posted	September 03, 2013
Recall Number	Z-2136-2013
Product	SC2316, Distal Femoral Augment with Screw Total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems and revision of failed previous reconstructions.
Code Information	Part number SC2316-3-5 with lot number 22389-111609. Part number SC2316-4-5 with lot number 22587-111609. Part number SC2316-5-5 with lot number 23214-111609.
Recalling Firm/ Manufacturer	Stelkast Co 200 Hidden Valley Rd Mcmurray, Pennsylvania 15317-2659
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Stelkast Customer Service 724-941-6368
Reason for Recall	The firm became aware of an incident relating to a breach of sterility in the sterility barrier packaging of SC2316, Distal Femoral Augment with Screw.
Action	Stelkast called and emailed all customers on June 24, 2013, to notify them of the recall. Customers were asked to recover all affected products from their inventory and return them to Stelkast. Customers were instructed to contact Stelkast Customer Service for a Return Authorization (RA) Number prior to shipment to Stelkast. Customers with questions were instructed to call 1-888-273-1583. For questions regarding this recall call 724-941-6368.
Quantity in Commerce	11
Distribution	Nationwide Distribution including TX, VA, OK, and PA

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18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfClia/Search.cfm
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21. 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/recallscorrectionsremovals/listofrecalls/default.htm&item2_text=fda%20enforcement%20report%20index&item2_url=www.fda.gov/safety/recalls/enforcementreports/default.htm