



رقم المحفوظات: ٤٧/٤٥  
رقم الصادر: ١٧/٢٤٤٦  
بيروت، في: ٢ تمزيقاً 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 ربطا:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



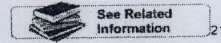




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**Class 2 Recall  
SC2316, Distal Femoral Augment  
with Screw**



<b>Date Posted</b>	September 03, 2013
<b>Recall Number</b>	Z-2136-2013
<b>Product</b>	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.
<b>Code Information</b>	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.
<b>Recalling Firm/ Manufacturer</b>	Stelkast Co 200 Hidden Valley Rd McMurray, Pennsylvania 15317-2659
<b>Consumer Instructions</b>	Contact the recalling firm for information
<b>For Additional Information Contact</b>	Stelkast Customer Service 724-941-6368
<b>Reason for Recall</b>	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.
<b>Action</b>	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.
<b>Quantity in Commerce</b>	11
<b>Distribution</b>	Nationwide Distribution including TX, VA, OK, and PA

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