الجهاز المعني بالمتاحة:

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

بناء على التقرير الصادر عن وكالة ال FDA والذي يشير إلى وجود خلل في عملية توضيب الصنف المذكور أعلاه مما قد يؤثر على فعالية التعقيم، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربط:

- التقرير الصادر عن وكالة ال FDA
- دائرة البرامج والمشاريع المستشفيات الحكومية
- المحفوظات
Medical & Radiation Emitting Device Recalls

510(k)\(1\) Registration & Listing\(1\) Adverse Events\(2\) Recalls\(3\) PMA\(4\) Classification\(5\) Standards\(6\) Inspections\(7\)
CFR Title 21\(8\) Radiation Emitting Products\(9\) X-Ray Assembler\(10\) Medical Reports\(11\) CLIA\(12\) TPLC\(13\)

New Search

Class 2 Recall
SC2316, Distal Femoral Augment
with Screw

Date Posted
September 03, 2013

Recall Number
Z-2198-2013

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 15317-2559

Consumer Instructions
Contact the recalling firm for information

For Additional
Information Contact
Stelkast Customer Service
724-941-6388

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 724-941-6388.

Quantity in Commerce
11

Distribution
Nationwide Distribution including TX, VA, OK, and PA

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmnm.cfm
8. /scripts/cdrh/cfdocs/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
12. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
14. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfClia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/cfRES.cfm?id=120308

9/18/2013