Medical & Radiation Emitting Device Recalls

Class 2 Recall
MicroFuse Bone Void Filler

Date Classified: October 31, 2013
Recall Number: Z-0123-2014
Product: Globus Medical MicroFuse Puffy, 2.5cc and 10cc. Product Usage: MicroFuse Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MicroFuse Bone Void Fillers a bone graft extender to be used with autogenous bone marrow aspirate or autograft.

Code Information: Part number 838.2025 (2.5cc), with lot # GBN299BB and expiration date October 2013, and lot # GBN355AB, with expiration date December 2013; and part # 838.2105 (10cc) with lot # GBN319AB, with expiration date November 2013.

Recalling Firm/Manufacturer: Globus Medical, Inc.
2560 General Armytud Ave
Audubon, Pennsylvania 19403-5214

For Additional Information Contact: Globus Medical Customer Service
610-930-1800

Manufacturer Reason for Recall: Sterility of this product to a Sterility Assurance Level (SAL) of 10(-4) cannot be assured.

Action: Globus sent an Urgent Medical Device Recall Notification letter, dated August 28, 2013 to customers/users. The letter identified the affected units, issue, potential risk, product, and actions to be taken. Customers were requested to complete the attached response card and return of the affected product to Globus Medical. For questions and support contact Globus Medical by fax 1-610-300-1342 or email: recall@globusmedical.com.

Quantity in Commerce: 193

Distribution: USA Nationwide Distribution.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfRLri.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfdocs/cfPMAP/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/cfCFRCFRSSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssemb/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsurm/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfO lia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tpic.cfm

Page Last Updated: 11/18/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=121916
11/19/2013