Class 2 Recall
MicroFuse Bone Void Filler

See Related Information[21]

Date Classified	October 31, 2013
Recall Number	Z-0123-2014
Product	Globus Medical MicroFuse Putty, 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 Fillerіs a bone graft extender to be used with autogenous bone marrow aspirate or autograft
Code Information	Part number 838.202S (2.5cc), with lot # GBN299BB and expiration date October 2013, and lot #GBN355AB, with expiration date December 2013: and part # 838.210S (10cc) with lot # GBN319AB, with expiration date November 2013, and GBN320BB with expiration date November 2013.
Recalling Firm/ Manufacturer	Globus Medical, Inc. 2560 General Armistead Ave Audubon, Pennsylvania 19403-5214
For Additional Information Contact	Globus Medical Customer Service 610-930-1800
Manufacturer Reason for Recall	The sterility of this product to a Sterility Assurance Level (SAL) of 10(-6) 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.

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