Class 2 Recall
Integra Bone Marrow Biopsy Trays

See Related Information[23]

Date Posted	October 30, 2015
Recall Status[1]	Open
Recall Number	Z-0193-2016
Recall Event ID	72274[24]
Premarket Notification 510(K) Number	K960248[25]
Product Classification	Syringe, Piston[26] - **Product Code** FMF[27]
Product	Integra® Bone Marrow Biopsy Trays Catalogue No. 3404253 Various medical devices and components used to perform bone marrow biopsies are placed in a plastic tray which is sealed in an EtO sterilizable pouch. Vials of 1 % Lidocaine HCL Injection, USP, 10 mg/mL (manufactured and distributed by Hospira Inc.) are placed in a separate sealed pouch. After the bone marrow biopsy pouch is sterilized, a Lidocaine pouch is affixed to each. Ten of these pouches are inserted in a sealed and labeled corrugated box.
Code Information	There are 3 Integra Lot Numbers affected by the recall of the single lot of Hospira Lidocaine: W1501193, W1504141, W1505078 Catalogue No. 3404253
Recalling Firm/ Manufacturer	Integra LifeSciences Corp. d.b.a. Integra Pain Management 3498 West 2400 South #1050 Salt Lake City, Utah 84119
Manufacturer Reason for Recall	Integra received an Urgent Drug Recall Notice from Hospira Inc. for their 1% Lidocaine HCL Injection, USP, 10 mg/mL, Lot 44-359-DK. Hospira Inc. is recalling vials of Lot 44-359-DK, 1% Lidocaine HCL Injection, USP, 10 mg/mLm distributed by Hospira from February 2015 to March 2015 due to a confirmed complaint of visible, partially embedded particulate within a single-dose glass teartop vial.
FDA Determined Cause [2]	PRODUCTION CONTROLS: Process Control
Action	Integra sent an Urgent Medical Device / Drug Recall Notice dated September 22, 2015, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Customers were instructed to forward copies of the Integra and Hospira recall notification letters to their customers. Confirmation of recall notification delivery and instructed to stop use of devices and return to Integra. If you have questions of a customer service nature or beyond the information in the Hospira Inc. URGENT DRUG PRODUCT RECALL NOTICE, please contact either your local Integra Pain Management Sales Representative or customer service at 1-800-241-2210.
Quantity in Commerce	A total of 470 packages (47 cases)
Distribution	US Distributed to the state of : MD.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]