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Class 2 Device Recall Pain Management Tray

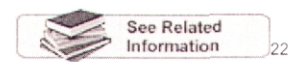


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Class 2 Device Recall Pain Management Tray



Date Initiated by Firm	June 21, 2017
Create Date	February 09, 2018
Recall Status¹	Open ³ , Classified
Recall Number	Z-0575-2018
Recall Event ID	<u>78878</u> ²³
Product Classification	<u>Needle, hypodermic, single lumen</u> ²⁴ - Product Code FMI ²⁵
Product	Pain Management Tray. Product Catalog Number: 560602. Local anesthesia of the skin prior to insertion of the regional anesthesia needle.
Code Information	0061522622., 0061537909.
Recalling Firm/Manufacturer	B. Braun Medical, Inc. 901 Marcon Blvd Allentown PA 18109-9512
For Additional Information Contact	610-596-0500
Manufacturer Reason for Recall	B. Braun Medical Inc. (BBMI) initiated this recall of various BBMI convenience kits containing the 22GA 1-1/2in SafetyGlide Needle due to the presence of loose polypropylene foreign matter was above release specification. This foreign matter has been identified as a product hub material which has been tested for biocompatibility per ISO 10993 during the product development process.
FDA Determined Cause²	Material/Component Contamination
Action	The firm, BD, sent an "URGENT MEDICAL DEVICE RECALL" letter dated 6/12/2017 to its customers/kit packers. B.Braun Medical Inc. (BBMI), sent a "VOLUNTARY MEDICAL DEVICE RECALL NOTIFICATION" letter dated 6/23/2017 to all BBMI customers in receipt of suspect product. Customers were notified by US Postal Service Certified Mail with registered return receipt mail or FedEx Priority. The letters described the product, problem and actions to be taken. The customers were instructed to review the device notification in its entirety and inform all users of the recall; determine your inventory of the affected product-Do not destroy any affected product; complete and return the "Product Removal Acknowledgement" form to B.Braun Medical Inc. Quality Assurance department via fax to 610-849-1197 or email to PA_QualityAssurance.BBMUS_Service@bbraun.com within two 2 weeks of receipt, even if the total inventory in your possession is zero 0; and if you have any full cases, partial cases or unused individual pieces a BBMI Customer Support Representative will contact you to provide instructions for handling affected product and arrange for return. Should you have any questions or concerns regarding the recall, please contact our Customer Support Department at 800-227-2862.
Quantity in Commerce	460 units
Distribution	US Nationwide Distribution.