## Class 2 Device Recall Custom Spinal Anesthesia Tray

**Date Initiated by Firm:** July 11, 2016  
**Create Date:** November 01, 2016  
**Recall Status:** Open, Classified  
**Recall Number:** Z-0327-2017  
**Recall Event ID:** 74879  
**Product Classification:** Tray, surgical  
**Product:** Affected Pain Control Tray Component (5% Lidocaine Hydrochloride and 7.5% Dextrose Injection, USP)  
**Code Information:** Catalog Number: 560399 (Lot # 0061418559, 0061422389, 0061434523, 0061438084, 0061440188, 0061446168, 0061450971, 0061459227, 0061464239), Catalog Number: 560511 (Lot # 0061413435, 0061425996, 0061438393, 0061452272, 0061465310), Catalog # 560605 (0061420240, 0061429962, 0061442280, 0061449510, 0061460497, 0061471580), Catalog # 560631 (Lot# 0061438803), Catalog # 560632 (0061438818).  
**Recalling Firm/Manufacturer:** B. Braun Medical, Inc.  
901 Marcon Blvd  
Allentown PA 18109-9512  
**For Additional Information Contact:** Customer Support Department  
800-227-2862  
**Manufacturer Reason for Recall:** B. Braun Medical Inc. is voluntarily recalling specific lots of their Custom Spinal Anesthesia Tray which contains a drug component, 5% Lidocaine Hydrochloride and 7.5% Dextrose Injection, USP that Hospira Inc. has recalled because the drug product does not meet the specification for color throughout shelf life.  
**FDA Determined Cause:** Under Investigation by firm  
**Action:** The firm, B.Braun, mailed to customers a "VOLUNTARY DRUG RECALL NOTIFICATION" letter dated July 12, 2016. The letter described the product, problem and actions to be taken and to inform the customers of a drug recall issued by Hospira, Inc. The Customers were instructed to determine their current inventory of the affected lots Do not destroy any affected product), complete and return "Product Removal Acknowledgement" form via fax to: B.Braun Medical Inc., Quality Assurance department at (610) 849-1197 or email to PA_QualityAssurance.BBMUS_Service@bbraun.com within two weeks of receipt, even if you have no inventory. A BBM Customer Service Representative will contact you to provide instructions for handling the affected product and arrange for return to BBM. Should you have any questions or concerns regarding the attached information, please contact our Customer Support Department at (800) 227-2862.  
**Quantity in Commerce:** 1704 units  
**Distribution:** US Distribution to: AL, IL, OK, MN, MA and WI.