Class 2 Recall Aesculap

See Related Information[21]

Date Posted	February 19, 2014
Recall Status[1]	Open
Recall Number	Z-0989-2014
Recall Event ID	67174[22]
Premarket Notification 510(K) Number	K120559[23]
Product Classification	Shunt, Central Nervous System And Components[24] - **Product Code** JXG[25]
Product	Aesculap proSA Adjustment Disc Size Large (L) The Miethke proSA Adjustment shunt system is intended to shut cerebrospinal fluid from the lateral ventricles of the brain into the peritoneum.
Code Information	4 lots: 4505268906, 4505336973, 4505408485, 4505238953
Recalling Firm/ Manufacturer	Aesculap, Inc. 3773 Corporate Pkwy Center Valley, Pennsylvania 18034-8217
For Additional Information Contact	Customer Support 800-258-1946 Ext. 5067
Manufacturer Reason for Recall	The accuracy is out of specification for the Aesculap proSA Adjustment Disc Size L.
FDA Determined Cause [2]	TRAINING: Employee Error
Action	Aesculap sent an Important Correction and Removal Notification dated December 23, 2013, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customers.. Yom"Aesculap Sales Representative will contact you to schedule a time to remove the FV795T from Set FV792T. Please use FV790T in the absence of the FV795T to ensure the correct adjustment has been made. Please complete the attached Inventory Sheet which is necessary to comply with FDA regulations. When completing the inventory sheet, please fill in the quantity being returned. If you cannot locate the product, please provide an explanation as to why the inventory will not be returned (discarded, etc.). AIC (USA) appreciates your cooperation on this matter and apologizes for the inconvenience this may cause. Thank you for your patience and continued support of this product. Please call (610) 984-9265 or (610) 984-9414 with any questions.
Quantity in Commerce	79
Distribution	Worldwide Distribution - US Distribution including the states of AZ, MD, MA, WI, MI, MN, DE, KS, and FL., and the countries of Australia, Germany, Great Britain, Norway and Japan.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.