See Related Information[22]

Class 2 Device Recall AESCULAP (FH620R) MINOP InVent 30 Trocar System

Date Initiated by Firm	March 07, 2017
Date Posted	March 20, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1814-2017
Recall Event ID	76769[23]
510(K)Number	K983365[24]
Product Classification	Endoscope, neurological[25] - **Product Code** GWG[26]
Product	AESCULAP MINOP InVent 30 Trocar System, non-sterile Product Usage:The Minop InVent Trocar System intended use is for endoscopic procedures within the central nervous system, especially for the treatment of intra- and paraventricular pathological structures.
Code Information	Item # FH620R
Recalling Firm/ Manufacturer	Aesculap Implant Systems LLC 3773 Corporate Pkwy Center Valley PA 18034-8217
For Additional Information Contact	Valerie Strawn 610-984-9414 Ext. 5414
Manufacturer Reason for Recall	Aesculap Implant Systems LLC is recalling the Minop Trocar due to the possibility it may have sharp edges on the distal end which may lead to the abrasion of the insulation when removing the electrode.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	On March 15, 2017, 16 facilities and 1 Sales Rep were sent an Urgent Medical Device Recall Notification letter. Letters were sent Fed-Ex overnight. Customers were asked to immediately discontinue use and quarantine the product. A Sales Representative will remove the affected product and return to Aesculap Inc.
Quantity in Commerce	21 units distributed in U.S.
Distribution	Product was distributed throughout the United States and Canada.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].