### 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**
Open, Classified

**Recall Number**
Z-1814-2017

**Recall Event ID**
7676823

**510(K) Number**
K98336524

**Product Classification**
Endoscope, neurological - Product Code GWG

**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 intraventricular 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 Straw
810-984-9414 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**
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

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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](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=154132).