Class 2 Device Recall Gomco Circumcision Clamps with separate ORing

New Search Back to Search Results

See Related Information[22]

Class 2 Device Recall Gomco Circumcision Clamps with separate ORing

Date Initiated by Firm	October 28, 2016
Create Date	January 05, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0947-2017
Recall Event ID	75937[23]
Product Classification	Clamp, circumcision[24] - **Product Code** HFX[25]
Product	Gomco Circumcision Clamps with separate O-Ring Component: The device is packaged non-sterile and has no shelf-life The Gomco clamp is intended to be used for circumcision surgeries
Code Information	Material Code MG096R (1.1 CM), MG097R (1.3 CM), MG227 (1.45CM), MG228 (1.6CM), MG229 (2.1 CM), MG230 (2.6CM).
Recalling Firm/ Manufacturer	Aesculap Implant Systems LLC 3773 Corporate Pkwy Center Valley PA 18034-8217
For Additional Information Contact	800-258-1946
Manufacturer Reason for Recall	Aesculap has received complaints of excessive bleeding after use of Gomco Circumcision Clamps.
FDA Determined Cause [2]	Under Investigation by firm
Action	Aesculap sent an Urgent Medical Device Recall Notification letter dated October 28, 2016, to all affected customers were sent an Urgent Medical Device Recall Notification letter via Fed-Ex overnight.. Customers were asked to immediately remove the affect product from their inventory and return to Aesculap. A return label was provided to efficiently remove and return the affected products. Customers with questions should call 610-984-9414. For questions regarding this recall call 800-258-1946.
Quantity in Commerce	437 units
Distribution	Nationwide Distribution
Total Product Life Cycle	TPLC Device Report[26]

[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[27].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.