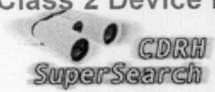


[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Class 2 Device Recall Gomco Circumcision Clamps with separate ORing**



[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall Gomco Circumcision Clamps with separate ORing**

[See Related Information](#)<sup>22</sup>

|   |   |
|---|---|
| <b>Date Initiated by Firm</b>             | October 28, 2016  |
| <b>Create Date</b>                        | January 05, 2017  |
| <b>Recall Status<sup>1</sup></b>          | Open <sup>3</sup> , Classified  |
| <b>Recall Number</b>                      | Z-0947-2017   |
| <b>Recall Event ID</b>                    | <a href="#">75937</a> <sup>23</sup>   |
| <b>Product Classification</b>             | <a href="#">Clamp, circumcision</a> <sup>24</sup> - <a href="#">Product Code HFX</a> <sup>25</sup>  |
| <b>Product</b>                            | Gomco Circumcision Clamps with separate O-Ring Component: The device is packaged non-sterile and has no shelf-life<br>The Gomco clamp is intended to be used for circumcision surgeries   |
| <b>Code Information</b>                   | Material Code MG096R (1.1 CM), MG097R (1.3 CM), MG227 (1.45CM), MG228 (1.6CM), MG229 (2.1 CM), MG230 (2.6CM).   |
| <b>Recalling Firm/Manufacturer</b>        | Aesculap Implant Systems LLC<br>3773 Corporate Pkwy<br>Center Valley PA 18034-8217  |
| <b>For Additional Information Contact</b> | 800-258-1946  |
| <b>Manufacturer Reason for Recall</b>     | Aesculap has received complaints of excessive bleeding after use of Gomco Circumcision Clamps.  |
| <b>FDA Determined Cause<sup>2</sup></b>   | Under Investigation by firm   |
| <b>Action</b>                             | 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. |
| <b>Quantity in Commerce</b>               | 437 units   |
| <b>Distribution</b>                       | Nationwide Distribution   |
| <b>Total Product Life Cycle</b>           | <a href="#">TPLC Device Report</a> <sup>26</sup>  |

<sup>1</sup> 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](#)<sup>27</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.