FDA



# Class 2 Device Recall Amplatz Extra Stiff Whisker Wire Guide

See Related Information[22]

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|---|---|
| **Date Initiated by Firm** | October 13, 2017 |
| **Create Date** | March 09, 2018 |
| **Recall Status[1]** | Open[3], Classified |
| **Recall Number** | Z-0947-2018 |
| **Recall Event ID** | 79195[23] |
| **Product Classification** | Wire, guide, catheter[24] - **Product Code** DQX[25] |
| **Product** | Amplatz Extra Stiff Whisker Wire Guide |
| **Code Information** | Catalog # THSCF-35-260-3-AESW-BH Affected lot codes range from: 3733552 - 6175191 F3729974 - F4923948 NS4927345 - NS6177894 |
| **Recalling Firm/ Manufacturer** | Cook Inc.<br>750 N Daniels Way<br>Bloomington IN 47404-9120 |
| **For Additional Information Contact** | Cook Medical Customer Relations Department<br>812-339-2235 |
| **Manufacturer Reason for Recall** | Label does not state that the product is heparin-coated. |
| **FDA Determined Cause [2]** | Labeling Change Control |
| **Action** | On October 31, 2017 an URGENT MEDICAL DEVICE CORRECTION was issued to customers requesting the following, including a corrective action: Step 1: Determine if your product is included in the affected lot ranges by comparing your lot number to the listing provided. " If your product is not affected, complete the Acknowledgement and Receipt Form. " If your product is affected, proceed to Step 2. Step 2: Remove a Heparin Coated label from the label sheet provided and apply to the top right corner of your affected unit. o If you need additional labels, please contact Stericycle at 855.215.4967. If you would like assistance, representatives are available to support you. To request assistance, please contact Stericycle at 855.215.4967 |
| **Quantity in Commerce** | 648 |
| **Distribution** | Nationally |
| **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.