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Class 2 Device Recall Amplatz Extra Stiff Whisker Wire Guide

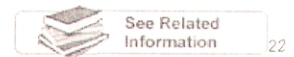


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Class 2 Device Recall Amplatz Extra Stiff Whisker Wire Guide



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. 750 N Daniels Way Bloomington IN 47404-9120
For Additional Information Contact	Cook Medical Customer Relations Department 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.