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Class 2 Device Recall Bivona Tracheostomy Tube Tracheostomy Tubes

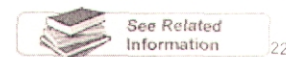


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Class 2 Device Recall Bivona Tracheostomy Tube Tracheostomy Tubes



Date Initiated by Firm	April 02, 2018
Create Date	June 07, 2018
Recall Status ¹	Open ³ , Classified
Recall Number	Z-2114-2018
Recall Event ID	80092 ²³
Product Classification	Tube, tracheostomy (w/wo connector) ²⁴ - Product Code BTO ²⁵
Product	Bivona _z Tracheostomy Tube Tracheostomy Tubes
Code Information	Part No. (Lot No.): CMZ3241N (DS009716), ST16EN80NSC194N (DS009794), SU15AN70NSC153N (DS009577), FT17IN60NGC114N (DS009894), CMZ3331N (DS009761), XU17GS50NSF046N (DS009609), FT17IN60NGC114N (DS009861), AA16ES70NSC110N (DS009586), FT17IN70NSC111N (DS009856), FT16IN60NGC053N (DS009540), FU15AN55NSA076N (DS009464), AT17IS60NGC105N (DS009811)
Recalling Firm/ Manufacturer	Smiths Medical ASD Inc. 6000 Nathan Ln N Minneapolis MN 55442-1690
For Additional Information Contact	763-383-3072
Manufacturer Reason for Recall	Carton labeling is printed with "Sterile" indicated labeling, however the device is not sold as sterile.
FDA Determined Cause ²	Error in labeling
Action	Customers were notified via letter on approximately 04/02/2018. Instructions included to determine if there are any affected Customized Bivona _z Tracheostomy Tubes in inventory, <i>notify customers if the devices have been further distributed, arrange for the return of affected devices, and complete and return the acknowledgement response form.</i>
Quantity in Commerce	16 units
Distribution	Domestic distribution to CA, FL, GA, ID, NJ, NM, OH, VA. International distribution to France.
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.