FDA

Class 2 Device Recall Cardiopulmonary Bypass Catheter Cannula and Tubing

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See Related Information[22]

Date Initiated by Firm	June 09, 2017
Create Date	August 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2871-2017
Recall Event ID	77699[23]
510(K)Number	K943934[24]
Product Classification	Catheter, cannula and tubing, vascular, cardiopulmonary bypass[25] - **Product Code** DWF[26]
Product	Sorin Group Aortic Arch Cannula, 7 mm x 10 in x 3/8 in, Rx Only, Sterile Product Usage: The Aortic Arch Cannulae are indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery.
Code Information	Model No. NA-1116, NA-1118, NA-1126, NA-1136, NA-1206, NA-1207, NA-1208, NA-1316, NA-1327, NA-1337, NA-1338, RA-1117, RA-1126, RA-1127, RA-1128A, RA-1136, RA-1137A, RA-1137, RA-1138, RA-1206; Lot No. 1407000078 to 1705200165, S140979 to S141841.
Recalling Firm/ Manufacturer	Sorin Group USA, Inc. 14401 W 65th Way Arvada CO 80004-3503
For Additional Information Contact	Joan Ceasar 281-228-7260
Manufacturer Reason for Recall	Identification of excess plastic on the tip of the cannula.
FDA Determined Cause [2]	Process control
Action	LivaNova sent an Urgent Medical Device letter dated June 16, 2017 to affected customers via certified mail or e-mail. The letter identified the affected product, problem and actions to be taken. The notice instructs customers to remove all recalled product from inventory and contact LivaNova Customer Support at 800-650-2623 to arrange for product return and replacement.
Quantity in Commerce	105,770 units
Distribution	Worldwide Distribution - US Nationwide in the states of : AR, AZ, CA, GA, IL, IN, KS, MI, MN, MO, NC, NE, NY, OK, PA, SD, TX, & VA. and foreign countries of: Canada, Iran, Mexico, & New Zealand.
Total Product Life Cycle	TPLC Device Report[27]