Class 2 Device Recall FlexFlowTM venous cannula Catalog 200200

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See Related Information[22]

Date Initiated by Firm	September 28, 2017
Create Date	November 08, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0076-2018
Recall Event ID	78331[23]
510(K)Number	K052081[24]
Product Classification	Catheter, cannula and tubing, vascular, cardiopulmonary bypass[25] - **Product Code** DWF[26]
Product	FlexFlow Venous Cannula Model/Catalog Number 200-200 The FlexFlow Venous Cannula is a single use sterile device. It is a size 23 French with an outside diameter of 0.30 inch (7.7 mm) and an effective working length of 11.2 inch (28.5 cm). The FlexFlow Venous Cannula is an open lumen polymer tube incorporating wire reinforcement in distal sections. The distal sections of the cannula are perforated with multiple openings to allow increased fluid flow. The clear proximal section is not reinforced to allow clamping the proximal end that terminates in a 3/8 inch (9.5 mm) barbed connector for standard cardiopulmonary bypass tubing. Each cannula is furnished with a mated obturator. Each obturator has a malleable wire. Each component is packaged inside a protective sheath in a single sterile, sealed pouch
Code Information	Lot: 181185; UDI: (01)10803622125812(240)200-200(17)200703(10)181185
Recalling Firm/ Manufacturer	Sorin Group USA, Inc. 14401 W 65th Way Arvada CO 80004-3503
Manufacturer Reason for Recall	A specific lot of the FlexFlowTM Venous Cannula, 200-200, is being recalled because it is sharper or pointier than expected.
FDA Determined Cause [2]	Process change control
Action	LivaNova sent an Urgent Medical Device Recall letter dated September 28 2017, to all affected consignees. The letter instructed customer to isolate products belonging to the lot involved. The level of the effectiveness check is Level A, where 100% of the consignees will be contacted. The customers were requested to send back any affected product and to complete the attached Customer Response Form by fax to 303-467-6502 or by email to USFSN@livanova.com. For questions customers were advised to contact Customer Service at 800-.650-2623.
Quantity in Commerce	40 units
Distribution	Worldwide Distribution - US (nationwide) Internationally to France and Spain
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA