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Class 2 Device Recall BioStable 5F DL55CM MST70 KIT NonValved PG

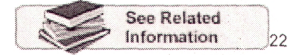


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Class 2 Device Recall BioStable 5F DL55CM MST70 KIT NonValved PG



Date Initiated by Firm	November 28, 2016
Create Date	December 14, 2017
Recall Status¹	Open ³ , Classified
Recall Number	Z-0247-2018
Recall Event ID	<u>76570</u> ²³
510(K)Number	<u>K150448</u> ²⁴
Product Classification	<u>Catheter, intravascular, therapeutic, long-term greater than 30 days</u> ²⁵ - Product Code <u>LJS</u> ²⁶
Product	Bio-Stable 5F DL-55CM MST-70 KIT Non-Valved PG, UPN H965458710, Catalog No. 45-871 The Xcela with PASV, BioFlo PICC with ENDEXO Technology, and BioFlo PICC with ENDEXO and PASV Valve Technology are indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications, nutrients; the sampling of blood; and for power injection of contrast media. Non-Valve lumens are indicated for central venous pressure monitoring.
Code Information	Lot 4903457
Recalling Firm/Manufacturer	Angiodynamics Inc. (Navilyst Medical Inc.) 10 Glens Falls Tech Park Glens Falls NY 12801-3864
For Additional Information Contact	518-792-4112
Manufacturer Reason for Recall	Navilyst Medical, Inc. (NMI) the manufacturer of the Xcela PICC with PASV, BioFlo PICC with PASV and the BioFlo PICC, conducted this recall to the end user level based on information received from Greatbatch Medical, the manufacturer of the ViaPeel PTFE Peelable Introducer. Greatbatch Medical determined that the products listed in their 11/11/2016 Recall Notification have the potential for the handles to detach from the sheath during use. NMI has confirmed that the affected sheaths, Greatbatch Model Number 10890-006, had been included in packaged Xcela and BioFlo PICC Kits.
FDA Determined Cause²	Component design/selection
Action	The firm, Navilyst Medical, sent an "URGENT VOLUNTARY MEDICAL DEVICE RECALL IMMEDIATE ACTION REQUIRED" letter dated 11/28/2016 by issuing recall notifications to consignees via Federal Express. The letter described the product, problems and actions to be taken. The Consignees were instructed to 1. IMMEDIATELY o Stop using the product subject to recall. o Remove any affected (recalled) product from your inventory (whether in labs, Central Supply, Shipping and Receiving or ANY other location). o Segregate this product in a secure location for return to Navilyst Medical, Inc. (an AngioDynamics Company) o Forward a copy of this recall notification to all sites to which you have distributed affected product. 2. Complete and return the Reply Verification Tracking Form. o If affected product is located in your institution, please call AngioDynamics Customer Service at 1-800-772-6446