# Class 2 Device Recall BioFlo PICC (NV) 5FDL55cm Maximal Barrier Nursing Kit

**Date Initiated by Firm**: May 10, 2018  
**Create Date**: June 14, 2018  
**Recall Status**: Open, Classified  
**Recall Number**: Z-2223-2018  
**Recall Event ID**: 8016923  
**510K Number**: K1634524  
**Product Classification**: Catheter, intravascular, therapeutic, long-term greater than 30 days  
**Product**: BioFlo PICC (NV) 5FDL-55cm Maximal Barrier Nursing Kit w/70cm Nitinol Wire PG, Catalog Number 75-033  
**Code Information**: UPN: H965750335, Lot: 5310029, 5310762  
**Recalling Firm/Manufacturer**: Angiodynamics Inc. (Nivalyst Medical Inc.)  
10 Glens Falls Tech Park  
Glens Falls NY 12801-3864  
**For Additional Information Contact**: David Greer  
518-795-1676  
**Manufacturer Reason for Recall**: A component of the kits might contain unsafe levels of bacterial endotoxins (pyrogens).  
**FDA Determined Cause**: Material/Component Contamination  
**Action**: Urgent Medical Device Recall letters were sent to customers on 5/10/18. The letters instructed customers to do the following: IMMEDIATELY Stop using the product subject to recall. Remove any affected (recalled) product from your inventory (whether in labs, Central Supply, Shipping and Receiving or ANY other location). Segregate this product in a secure location for return to AngioDynamics, Inc. Forward a copy of this recall notification to all sites to which you have distributed affected product. Complete and return the Reply Verification Tracking Form. If affected product is located in your institution, please call AngioDynamics Customer Service at 1-800-772-6446 between 8:00 a.m. and 7:00 p.m. (Monday - Friday, Eastern Standard Time) to obtain a replacement or credit for your returned product.  
**Quantity in Commerce**: 81 boxes  
**Distribution**: The products were distributed to the following US states: AZ, CA, CO, CT, DC, FL, GA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, MT, NC, ND, NJ, NM, NV, NY, OH, OK, OR, PA, SC, TN, TX, WA, WI, and WV. The products were distributed to the following foreign countries: Canada, China, Ireland, Spain.  
**Total Product Life Cycle**: TPLC Device Report

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