Class 2 Recall FemFlex II Pediatric Femoral Arterial Cannula

See Related Information[23]

Date Posted	April 02, 2015
Recall Status[1]	Open
Recall Number	Z-1371-2015
Recall Event ID	70820[24]
Premarket Notification 510(K) Number	K140208[25]
Product Classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass[26] - **Product Code** DWF[27]
Product	Edwards Lifesciences Fem-Flex II Femoral Arterial Cannula 8, 10, 12 French,Sterile EO, Rx Only, Manufacturer Edwards Lifesciences LLC, Irvine, CA.-Model Numbers: FEMII008A, FEMII008AT, FEMII008V, FEMII010A, FEMII010AT, FEMII010V, FEMII012A, FEMII012AT, and FEMII012V. Edwards Femoral Access Cannulae are intended to provide a means of draining the blood flow (venous), or perfusing blood into the body (arterial) of a patient during cardiopulmonary bypass procedures.
Code Information	Model/Lot Numbers: FEMII008A/59751073, 59775775, 59775776, 59775777 & 59852930; FEMII008AT/59807985, 59867050, & 59873263; FEMII008V/59873250 & 59873251; FEMII010A/59740468, 59773806, 59792415, 59792416 & 59852934; FEMII010AT/ 59747819, 59807986,59852935, 59890916 & 59896910; FEMII010V/59751074, 59849119 & 59890924; FEMII012A/ 59801792,59867064, 59884766 & 59884778 FEMII012AT/59852940 & 59867051; and FEMII012V/59723307, 59796683, 59849124 & 59873252
Recalling Firm/ Manufacturer	Edwards Lifesciences, LLC 12050 Lone Peak Pkwy Draper, Utah 84020-9414
For Additional Information Contact	Sherri L. Robbins 801-553-7531
Manufacturer Reason for Recall	Edwards Lifesciences is recalling Fem-Flex II Pediatric Femoral Arterial Cannula sizes 8, 10, 12 French because of the potential of tissue damage caused by a protruding wire located at the tip of the cannula.
FDA Determined Cause [2]	CHANGE CONTROL (GMP - GOOD MANUFACTURING PRACTICE): Process Change Control
Action	The firm, Edwards, sent an "URGENT - PRODUCT RECALL - ACTION REQUIRED" letter dated March 23, 2015 via FED EX on March 27, 2015 to their customers. The letter described the product, problem, and actions to be taken. The customers were instructed to review entire inventory for the lots listed; complete and return attached acknowledgment form via fax to Edwards Customer Service at 800.422.9329. within three days of receipt of this Field Safety Notice; contact Customer Service at 800.422.3278 to obtain an RGA number and replacement product; return affected product to Edwards Lifesciences, Attn: Cirilo Chaparro, 12050 Lone Peak Drive, Draper, UT 84020, Attention: RECALL, RGA#XXX; and transfer this notice to other organizations if the affected devices have been transferred to any another facilities. If you have any questions that have not been answered by this letter, please call Edwards Customer Services at 800.424.3278 from the hours of 6:00AM - 4:30PM PST; Edwards Customer Service at (800) 268-3993 from 8:00AM 4:30PM Eastern Time or contact your Edwards sales representative concerning the recall.