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From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, February 12, 2016 12:41 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: FDA Safety Alert - Central Venous Catheters and Pressure Monitoring Sets and Trays by Cook Medical: Recall - Catheter Tip Fracture and/or Separation

Central Venous Catheters and Pressure Monitoring Sets and Trays by Cook Medical: Recall - Catheter Tip Fracture and/or Separation

- Single Lumen Central Venous Catheter Sets and Trays
- Single Lumen Pressure Monitoring Sets
- Femoral Artery Pressure Monitoring Catheter Sets and Trays
- Radial Artery Pressure Monitoring Catheter Sets and Trays

ISSUE: During an internal inspection, a catheter exhibited the potential for catheter tip fracture and/or separation. Further investigation revealed that the technique used by the product assembler while tipping the catheter likely contributed to this nonconformance. No reports of illness or injury have been associated with this issue to date.

Potential adverse events that may occur as a result of catheter tip fracture and/or separation include loss of device function, the need for medical intervention to retrieve a separated segment, and complications resulting from a separated tip occluding blood flow to end organs. Examples of such complications include stroke, kidney injury, or damage to the intestines or limbs.

The Single Lumen Central Venous Catheters and Pressure Monitoring Sets and Trays in this recall were distributed globally between April 24, 2015, and October 23, 2015. Product can be identified by the part number and lot number that are provided on the outer package product label. See the Press Release for a listing of affected lot numbers.

BACKGROUND: These products are intended for use in venous or arterial pressure monitoring, blood sampling, and administration of drugs and fluids.

RECOMMENDATION: Cook Medical notified its customers and distributors by recall notification letters in January. All customers and distributors should quarantine and discontinue use of all affected units and return the affected product to the company as soon as possible for credit.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch Safety Alert, including a link to the press release, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm485910.htm

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

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