Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, October 05, 2016 1:15 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Twin-Pass Dual Access Catheters by Vascular Solutions: Recall - Potential for Excess Manufacturing Material At The Tip

ISSUE: Vascular Solutions, Inc., initiated a nationwide recall (Sept. 16, 2016) of Twin-Pass Dual Access catheters used in catheterization procedures. All unexpired lots of the product have been recalled because there is a potential for excess manufacturing material to remain at the tip of the catheter or within the distal portion of the rapid exchange lumen. It is possible that the excess material may separate from the catheter during use and pose a potential risk of embolism, which could result in serious injury or death. No injuries have been reported in association with this issue to date.

BACKGROUND: The recalled products were manufactured from October 2014 to August 2016 and distributed from October 2014 to September 2016. The recalled products are all unexpired lots of Model Numbers 5200, 5210, and 5230. A listing of the recalled lots is available from Vascular Solutions and has been provided to each facility that purchased the affected products. A total of 15,896 devices have been manufactured, with 5,784 distributed in the United States and currently unexpired. The condition that led to the recall may affect approximately 9.2% of recalled devices.

RECOMMENDATION: Healthcare facilities that have the affected Twin-Pass dual access catheters should remove the products from their inventory and return them to Vascular Solutions.

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/ucm524109.htm