From:	Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Cc:	Pharmacy_Subscriberlist@DCA
Subject:	FDA MedWatch - Roadrunner UniGlide Hydrophilic Wire Guides by Cook Medical: Recall - Raw Materials Issue
Date:	Wednesday, September 07, 2016 9:16:06 AM

Roadrunner UniGlide Hydrophilic Wire Guides by Cook Medical: Recall - Raw Materials Issue

AUDIENCE: Cardiology, Risk Manager, Pharmacy

ISSUE: DSM Biomedical B.V., the Netherlands, Cook Medical's supplier of hydrophilic coating for the Roadrunner Uniglide Hydrophilic Wire Guide, recalled certain lots of material due to concerns about a potential contamination by glass particles ranging in size of approximately 4 to 280 µm. Cook received one lot of the affected recalled coating. This prompted Cook Medical to initiate a recall of 8,750 units of the Roadrunner UniGlide Hydrophilic Wire Guides on June 24, 2016. Cook is taking this action as a precautionary measure, because it cannot exclude the possibility that glass particles passed through during processing and could be present in the coating of the recalled wire guide units.
Potential adverse events that may occur as a result of this contamination could include vessel damage, bleeding and embolic particulate in the circulatory system. Cook Medical has not received any reports of adverse events of these types to date.

BACKGROUND: The Roadrunner UniGlide Hydrophilic Wire Guide is intended for use in the delivery of percutaneous catheters into the peripheral vasculature. A full list of affected products and lot numbers can be found in the recall notice. Products can be identified by the part number and lot number on the outer label of the package. Products in this recall were distributed globally.

RECOMMENDATION: Cook Medical has notified its customers and distributors by recall notification letters. The letters requested that all customers and distributors quarantine and discontinue use of all recalled units and return the affected products to Cook as soon as possible for credit.

Consumers with medical questions or concerns should contact Cook Medical Customer Relations at 1-800-457-4500 or 1-812-339-2235, Monday through Friday, between 7:30 a.m. and 5:00 p.m. Eastern time. For information regarding the recall, please contact Stericycle Expert Solutions at 1-866-912-9552.
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 link to the Recall notice, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm516741.htm