From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, May 04, 2017 7:28 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: ReFlow Medical Issues Recall of Specific Lots of Wingman35 Crossing Catheters

For Immediate Release

May 3, 2017

Contact

Consumers

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Announcement

On April 22, 2017, ReFlow Medical initiated a lot-specific voluntary recall of the Wingman35 Crossing Catheters.

The FDA is classifying this as a Class 1 recall, the most serious recall situation where the patient is exposed to a reasonable likelihood of death or a serious injury. The Wingman35 Crossing Catheters have been found to exhibit tip splitting or separation, which has resulted in two adverse events. ReFlow has received 2 complaints of catheter-tip splitting and/or separation. A total of 2327 Wingman catheters are in distribution.

Tip splitting has the potential to lead to loss of device function. Tip separation may require medical intervention to retrieve a separated segment or may occlude blood flow to end organs.

The Wingman Crossing Catheters in this recall were distributed between January 2015 and March 2016.

ReFlow 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 potentially affected units and return the affected product to the company as soon as possible for credit.

FDA and other regulatory agencies around the world have been notified of this action.

Consumers with questions may contact ReFlow Medical Customer Relations at 1-949-481-0399, Monday through Friday, between 8:00 a.m. and 4:30 p.m. Pacific time or by email at info@reflowmedical.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report Online: www.fda.gov/medwatch/report.htm Regular mail or fax: Download form

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