

Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, October 30, 2015 3:58 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Myocardial Protection System (MPS) Delivery Sets by Quest Medical: Recall - Intermittent Seal Failure During Use

The identified lots of MPS Delivery sets have shown a possible seal failure along the blood source channel of main pump cassette, resulting in blood loss from the bypass circuit and interruption of cardioplegia solution delivery. The firm has received twenty complaints alleging this seal failure which have resulted in 16 instances of patient blood loss during surgery. There have been no reports of patient injuries as a result of the alleged issue to date.

Recalled Product(s) were manufactured from May 2015 to September 2015 and distributed from June 2015 to September 2015. See the [Press Release](#) for affected lot numbers.

BACKGROUND: The affected product lot information can be identified by product labeling on shipper and individual sterile trays.

RECOMMENDATION: Consumers who have the applicable lots of the MPS Delivery Set(s) should cease use of the affected lots and contact Quest Medical, Inc. to return the product and request replacement. Additionally, consignees are being notified via written correspondence.

Consumers with questions may contact the company via telephone at 1-800-627-0226 Monday through Friday between the hours of 9am and 5pm (CT). Consumer may also contact the company via e-mail at custserv@questmedical.com.

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

[10/29/2015 - [Press Release](#) - Quest Medical]