Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, January 12, 2016 4:54 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Pleural and Pneumopericardial Drainage Sets by Stryker Fuhrman - Class I Recall - Catheter May Break During Insertion

Stryker Sustainability Solutions received two reports that the catheter included in the Drainage Set broke off in the pleural cavity while inserting the device into the patient. Both cases resulted in the need for medical intervention. This issue could cause serious patient injury or death.

See the Recall Notice for further information, including manufacturing dates, distribution dates, and lot numbers.

BACKGROUND: The Fuhrman Pleural/Pneumopericardial Drainage Set is used to remove air from the sac (pericardium) surrounding the heart, or to drain air or fluid from thin covering (pleural cavity) that protects the lungs.

RECOMMENDATION: Stryker sent customer notification letters on November 17, 2015. The letter indicated that customers should:

- Discontinue use of the product
- Complete the Recall Effectiveness Check Form even if no product has been found in inventory
- Return the form to their local Stryker Sustainability Sales Representative via email at ssspfa@stryker.com or mail to: Stryker Sustainability Solutions, 1810 West Drake Drive Tempe, AZ 85283 Attn: Jodie Rueckert
- If the firm indicates that affected devices remain in inventory, a prepaid shipping label will be issued for the return of the product.
- Customers will receive credit for all affected devices returned.

Customers with questions should contact the Stryker Sustainability Solutions Complaint Hotline: 1(888) 888-3433 x5555.

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

[01/11/2016 - Recall Notice - FDA]