Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, December 14, 2015 9:27 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Chariot Guiding Sheath by Boston Scientific: Recall - Risk of Shaft Separation

Boston Scientific has recalled the Chariot Guiding Sheath globally. The recall affects all UPNs of the Chariot Guiding Sheaths. The recall was initiated on November 19, 2015 due to the risk of shaft separation.

To date, Boston Scientific has received fourteen complaints for shaft separation, four of which involved separation of the distal shaft. These events occurred during device preparation or use. The most severe outcome of this failure is embolism of device fragments, which could lead to obstruction of blood flow or additional intervention to remove a device fragment. Obstruction of blood flow can result in injuries such as stroke, kidney damage or damage to the intestines or limbs.

BACKGROUND: These devices are intended for the introduction of interventional devices during peripheral vascular procedures.

RECOMMENDATION: All affected healthcare facilities were previously advised to immediately discontinue use of affected devices and return unused Chariot Guiding Sheaths to Boston Scientific. Additionally, physicians are encouraged to contact all patients who have undergone procedures involving Chariot to confirm their post-procedure status, as device shaft separation and embolized fragments may not have been recognized at the time of the procedure.

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

[12/09/2015 - Press Release - Boston Scientific]