Boston Scientific

Voluntary Recall of Chariot™ Guiding Sheath

MARLBOROUGH, Mass., Dec. 9, 2015 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has voluntarily recalled the Chariot™ Guiding Sheath globally. These devices are intended for the introduction of interventional devices during peripheral vascular procedures, and were recalled on November 19th due to the risk of shaft separation. The U.S. Food and Drug Administration (FDA) has classified the action as a Class-1 recall.

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. To date, no permanent injuries or patient deaths have been reported.

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.

The recall affects all UPNs of the Chariot Guiding Sheaths. Customers have been advised to remove the affected recalled product from inventory and return it to Boston Scientific.

H74939277645110	H74939277745110	H74939277845110	H74939277645220	H74939277765120
H74939277690210	H74939277665110	H74939277790110	H74939277645120	H74939277865120
H74939277690220	H74939277690110	H74939277865110	H74939277745120	H74939277890120
H74939277845210	H74939277765110	H74939277545210	H74939277790210	H74939277845120
H74939277745210	H74939277545110	H74939277790220	H74939277790120	H74939277745220
H74939277645210	H74939277690120	H74939277665120	H74939277890110	

Physicians and healthcare facilities can direct questions to their Boston Scientific representative or by calling 1-800-811-3211. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA 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, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

or

- Health care professionals and consumers may report serious adverse events or product quality problems with the use of this product to Boston Scientific by calling 1-800-811-3211 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

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