Class 1 Recall Chariot" Guiding Sheath

See Related Information[22]

Date Posted	December 18, 2015
Recall Status[1]	Open
Recall Number	Z-0392-2016
Recall Event ID	72702[23]
Premarket Notification 510(K) Number	K150186[24]
Product Classification	Introducer, Catheter[25] - **Product Code** DYB[26]
Product	Boston Scientific, Chariot ST-CCV Guiding Sheath, Sterilized using ethylene oxide: Product Description Material Number (UPN) Guiding Sheath 5F, 45 cm, ST, CC H74939277545110 Guiding Sheath 5F, 45 cm, MP, CC H74939277545210 Guiding Sheath 6F, 45 cm, ST, CC H74939277645110 Guiding Sheath 6F, 45 cm, ST, TB H74939277645120 Guiding Sheath 6F, 45 cm, MP, CC H74939277645210 Guiding Sheath 6F, 45 cm, MP, TB H74939277645220 Guiding Sheath 6F, 65 cm, ST, CC H74939277665110 Guiding Sheath 6F, 65 cm, ST, TB H74939277665120 Guiding Sheath 6F, 90 cm, ST, CC H74939277690110 Guiding Sheath 6F, 90 cm, ST, TB H74939277690120 Guiding Sheath 6F, 90 cm, MP, CC H74939277690210 Guiding Sheath 6F, 90 cm, MP, TB H74939277690220 Guiding Sheath 7F, 45 cm, ST, CC H74939277745110 Guiding Sheath 7F, 45 cm, ST, TB H74939277745120 Guiding Sheath 7F, 45 cm, MP, CC H74939277745210 Guiding Sheath 7F, 45 cm, MP, TB H74939277745220 Guiding Sheath 7F, 65 cm, ST, CC H74939277765110 Guiding Sheath 7F, 65 cm, ST, TB H74939277765120 Guiding Sheath 7F, 90 cm, ST, CC H74939277790110 Guiding Sheath 7F, 90 cm, ST, TB H74939277790120 Guiding Sheath 7F, 90 cm, MP, CC H74939277790210 Guiding Sheath 7F, 90 cm, MP, TB H74939277790220 Guiding Sheath 8F, 45 cm, ST, CC H74939277845110 Guiding Sheath 8F, 45 cm, ST, TB H74939277845120 Guiding Sheath 8F, 45 cm, MP, CC H74939277845210 Guiding Sheath 8F, 65 cm, ST, CC H74939277865110 Guiding Sheath 8F, 65 cm, ST, TB H74939277865120 Guiding Sheath 8F, 90 cm, ST, CC H74939277890110 Guiding Sheath 8F, 90 cm, ST, TB H74939277890120 Product Usage: The Chariot Guiding Sheath is designed to perform as an introducer sheath for delivering interventional and diagnostic devices into the peripheral vasculature. The guiding sheath has a coiled shaft design and comes with a straight or preformed multipurpose tip shape. It is equipped with a cross-cut hemostatic valve or Tuohy-Borst adapter to prevent bleeding and a sidearm with a three-way stopcock to allow for flushing and introduction of contrast medium. It is packaged with a dilator to facilitate delivery over a guidewire. The guiding sheath can accommodate guidewires with diameters less than or equal to 0.038 in (0.97 mm). The outer surface of the guiding sheath has a hydrophilic coating from the distal tip to approximately 9 cm from the hub. The distal tip has a radiopaque marker band approximately 6 mm from the distal edge, to help with guiding sheath placement.
Code Information	Batch 17797683 17797684 17797685 17797686 17797687 17797688 17797689 17797690 17797691 17797692 17797693 17797694 17797695 17797696 17797697 17798268 17798269 17798270 17798271 17798272 17798273 17806530 17829972 17829976 17830219 17839346 17839347 17839350 17866538 17866881 17866882 17872044 17872045 17915368 17915369 17940916 17941111 17943786 17945064 17945224 17946351 17949277 17950404 17951572 17952749 17953534 17958093 17958489 17961473 17962740 17966591 17971123 17972092 17972761 17976335 17977575 17978575 17981064 17983006 17983027 17984693 17985812 17986420 17987381 17989008 17990047 17991170 17991321 17994529 17995087 17996706 17997093

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Recalling Firm/ Manufacturer	Boston Scientific Corporation 2 Scimed Pl Maple Grove, Minnesota 55311-1565
For Additional Information Contact	Nicole Pshon 763-494-1556
Manufacturer Reason for Recall	Boston Scientific is voluntarily recalling its Chariot" Guiding Sheath. To date, Boston Scientific has received fourteen complaints for shaft separation, four for distal shaft separation. The most severe outcome of this failure is embolism of device fragments.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	Consignees were sent a Boston Scientific "Urgent Medical Device Recall Removal" letter dated November 19, 2015. The letter was addressed to Materials Manager /Field Action Contact. The letter described the problem and the product involved in the recall. Advised consignees to segregate and return affected product to Boston Scientific. Requested consignees to complete and return the "Recall Removal Reply Verification Tracking Form" to MapleGroveFieldActionCenter@bsci.com or fax to 1-866-213-1806.
Quantity in Commerce	7985
Distribution	Worldwide Distribution - US (nationwide) including DC and Puerto Rico, and in the states of AK, AL, AR. AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, MA, MD, ME, MI, MO, MS, NC, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, VA, WA, WI, WV, and WY and the countries of Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Hong Kong, Hungary, Ireland, Italy, Luxembourg, Macedonia, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and Ukraine.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = DYB and Original Applicant = BOSTON SCIENTIFIC CORP.[29]

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