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### Class 1 Device Recall Chariot" Guiding Sheath

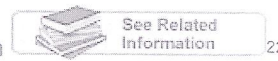


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### Class 1 Recall Chariot" Guiding Sheath



<b>Date Posted</b>	December 18, 2015
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-0392-2016
<b>Recall Event ID</b>	<u>72702</u> <sup>23</sup>
<b>Premarket Notification 510(K) Number</b>	<u>K150186</u> <sup>24</sup>
<b>Product Classification</b>	Introducer, Catheter <sup>25</sup> - Product Code <u>DYB</u> <sup>26</sup>

**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**

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<b>Recalling Firm/ Manufacturer</b>	Boston Scientific Corporation 2 Scimed Pl Maple Grove, Minnesota 55311-1565
<b>For Additional Information Contact</b>	Nicole Pshon 763-494-1556
<b>Manufacturer Reason for Recall</b>	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.
<b>FDA Determined Cause <sup>2</sup></b>	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
<b>Action</b>	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 <a href="mailto:MapleGroveFieldActionCenter@bsci.com">MapleGroveFieldActionCenter@bsci.com</a> or fax to 1-866-213-1806.
<b>Quantity in Commerce</b>	7985
<b>Distribution</b>	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.
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>27</sup>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)<sup>28</sup>

<sup>2</sup> 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.<sup>29</sup>

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