Date Initiated by Firm: December 11, 2017
Create Date: August 08, 2018
Recall Status: Open, Classified
Recall Number: Z-2735-2018
Recall Event ID: 8051323
510(K)Number: K01085324 K98045325
Product Classification: Catheter, percutaneous
Product: Boston Scientific Guider Softip XF Guide Catheter

Product Usage:
Is a neurovascular access catheter that creates a stable conduit through which interventional devices can pass. It is constructed with a polymer liner on the inside diameter for lubricity, stainless steel wire reinforcement within the wall for torque transmission and strength, and polymer materials along the length of the catheter for support and flexibility. The catheter has an atraumatic tip and a hub/strain relief combination for kink resistance (at the hub), device connectivity, and device handling.

Code Information
Product Batch: GUIDER/40DEG XF/7FR/90CM 17987235 GUIDER/40DEG XF/7FR/90CM 17997088 GUIDER/40DEG XF/7FR/90CM 18056237 GUIDER/40DEG XF/7FR/90CM 18056695 GUIDER/40DEG XF/7FR/90CM 18056772 GUIDER/40DEG XF/7FR/90CM 18070824 GUIDER/40DEG XF/7FR/90CM 18070877 GUIDER/40DEG XF/7FR/90CM 18087352 GUIDER/40DEG XF/7FR/90CM 18081509 GUIDER/40DEG XF/7FR/90CM 18082040 GUIDER/40DEG XF/7FR/90CM 18082155 GUIDER/40DEG XF/7FR/90CM 16090719 GUIDER/40DEG XF/7FR/90CM 16091068 GUIDER/40DEG XF/7FR/90CM 16091155 GUIDER/40DEG XF/7FR/90CM 16092066 GUIDER/40DEG XF/7FR/90CM 16093344 GUIDER/40DEG XF/7FR/90CM 16096359 GUIDER/40DEG XF/7FR/90CM 18106576 GUIDER/40DEG XF/7FR/90CM 18107079 GUIDER/40DEG XF/7FR/90CM 18107320 GUIDER/40DEG XF/7FR/90CM 18107526 GUIDER/40DEG XF/7FR/90CM 18116096 GUIDER/40DEG XF/7FR/90CM 18116710 GUIDER/40DEG XF/7FR/90CM 18122629 GUIDER/40DEG XF/7FR/90CM 18122904 GUIDER/40DEG XF/7FR/90CM 18123050 GUIDER/40DEG XF/7FR/90CM 18123182 GUIDER/40DEG XF/7FR/90CM 18124574 GUIDER/40DEG XF/7FR/90CM 18124635 GUIDER/40DEG XF/7FR/90CM 18231878 GUIDER/40DEG XF/7FR/90CM 18250466 GUIDER/40DEG XF/7FR/90CM 18253010 GUIDER/40DEG XF/7FR/90CM 18270467 GUIDER/40DEG XF/7FR/90CM 18270475 GUIDER/40DEG XF/7FR/90CM 18277426 GUIDER/40DEG XF/7FR/90CM 18277497 GUIDER/40DEG XF/7FR/90CM 18277458 GUIDER/40DEG XF/7FR/90CM 18277529 GUIDER/40DEG XF/7FR/90CM 18285135 GUIDER/40DEG XF/7FR/90CM 18278516 GUIDER/40DEG XF/7FR/90CM 18278572 GUIDER/40DEG XF/7FR/90CM 18278539 GUIDER/40DEG XF/7FR/90CM 18283612 GUIDER/40DEG XF/7FR/90CM 18283716 GUIDER/40DEG XF/7FR/90CM 18283719 GUIDER/40DEG XF/7FR/90CM 18283763 GUIDER/40DEG XF/7FR/90CM 18284986 GUIDER/40DEG XF/7FR/90CM
Manufacturer
2 Scimed Pl
Maple Grove MN 55311-1565

For Additional Information Contact
Nicole Pshon
763-494-1133

Manufacturer Reason for Recall
Potential polymer material degradation.

FDA Determined Cause
Process change control

Action
On December 11, 2017, Stryker Neurovascular sent notification to all their customers informing them of the recall. Included in a letter to be sent to each affected account which includes instructions to return product to Stryker and Form to be completed by customers to document products which have been consumed and products to be returned to Stryker. Return the completed form to your nominated Stryker Representative or to N/FieldActions@stryker.com.

Quantity in Commerce
31,005

Distribution
Worldwide - US Nationwide Distribution - AL, FL, IL, IN, KY, MA, MI, MN, MS, NC, NV, NY, OH, OR, TN, TX, UT, WA and the country CANADA

Total Product Life Cycle
TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls.

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall. The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database
510(K)s with Product Code = DQY and Original Applicant = BOSTON SCIENTIFIC, SCIMED, INC.
510(K)s with Product Code = DQY and Original Applicant = BOSTON SCIENTIFIC, TARGET

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=165651 8/20/2018