Class 2 Device Recall Tearaway Introducer

See Related Information[22]

Recall Date	June 07, 2016
Recall Status[1]	Open
Recall Number	Z-1924-2016
Recall Event ID	74176[23]
510(K)Number	K130687[24]
Product Classification	Introducer, catheter[25] - **Product Code** DYB[26]
Product	Tearaway Introducer, Model # VS203, VS303, 510 K # 130687, packaged individually in a pouch, 5 pouches per carton, lot # MBZ140, MBZL450, MBZV930 MBZZ490 Product Usage: The 2F and 3F Vascu-Sheath Tearaway Introducer is intended for percutaneous venous access by modified Seldinger Technique in neonates, infants and children.
Code Information	Catalog Numbers/Lot Numbers/Exp. Date/UDI Number: VS203 Lot # MBZX140 exp. date 01/18/2021 UDI# 884908105209 VS303 Lot # MBZL450 exp. date 11/14/2020 UDI# 884908105216 VS303 Lot # MBZV930 exp. date 11/01/2021 UDI# 884908105216 VS303 Lot # MBZZ490 exp. date 01/28/2021 UDI# 884908105216
Recalling Firm/ Manufacturer	Medical Components, Inc dba MedComp 1499 Delp Dr Harleysville PA 19438-2936
For Additional Information Contact	Susan M. Smith 215-256-4201
Manufacturer Reason for Recall	This recall has been initiated due to the product labeled with the incorrect expiration date.
FDA Determined Cause [2]	Labeling mix-ups
Action	MedComp sent a Product Recall letter dated May 5, 2016 to customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to evaluate their inventory and quarantine for the return of all un-used affected product. They were asked to contact Customer Service for a Return Goods Authorization (RGA) number at 215-256-9191.
Quantity in Commerce	VS203 Lot# MBZX140 (100 units); VS303 Lot # MBZL450 (60 units); VS303 Lot # MBZV930 (65 units); VS303 Lot # MBZZ490 (33 units).
Distribution	US Distributed to: FL, TX, NC
Total Product Life Cycle	TPLC Device Report[27]

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[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.