



Class 2 Device Recall VenaSeal Closure System

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Class 2 Recall VenaSeal Closure System



Date Posted	May 12, 2015
Recall Status¹	Open
Recall Number	Z-1599-2015
Recall Event ID	71138
Product Classification	Agent, Occluding, Vascular, Permanent - Product Code PJQ
Product	VenaSeal, Sapheon Closure System, Model # SP-101, VS-301 and VS-402. For vascular use.
Code Information	Model no. SP-101, Lots, 35766, 36191, 36192, 36617, 36618, 37621, 37622, 37399, 37400, 38263, 38286, 38407, 38417, 38756, 38863, 38864, 39113, 39336, 39378, 39670, 39739, 39848 and 40075.; Model no. VS-301, Lots 34193, 35585, 37007, 38804, 39111, 39123, 39469 and 40160; Model no. VS-402, Lots 39970, 39971, 39972, 39973, 40067, 40069, 40187, 40243, 40271 and 40272.
Recalling Firm/ Manufacturer	Covidien LLC 15 Hampshire St Mansfield, Massachusetts 02048-1113
For Additional Information Contact	Carlos Alfonzo 508-261-8000
Manufacturer Reason for Recall	Possible sterility breach of the outer packaging (pouch) material which may compromise the outside surface sterility of the sealed inner tray.
Action	Consignees were contacted by letter via email on April 28, 2015.
Quantity in Commerce	1661 units
Distribution	Worldwide distribution. No U.S. accounts; Australia, Canada, France, Germany, Hong Kong, Ireland, Italy, Latvia, Netherlands, Norway, Portugal, Switzerland, UAE and the United Kingdom.
Total Product Life Cycle	TPLC Device Report

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

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