Class 1 Recall Covidien Trellis 6 Peripheral Infusion System

See Related Information[22]

Date Posted	February 03, 2015
Recall Status[1]	Open
Recall Number	Z-1017-2015
Recall Event ID	70048[23]
Premarket Notification 510(K) Number	K071664[24]
Product Classification	Catheter, Continuous Flush[25] - **Product Code** KRA[26]
Product	Covidien Trellis-6 Peripheral Infusion System. Models BVT608010V01, BVT608030V01, BVT612010V01, and BVT612030V01. Sterile EO. Product Usage: Intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.
Code Information	Model BVT608010, Lot numbers: 9853174, 9864497, 9890772, 9890931, 9925676, 9932672, 9937308, 9937315, 9940474, 9940614, 9976340, 9978233, A001589, A001740. Model BVT608030, Lot Numbers: 9853331, 9887597, 9887695, 9887757, 9932042. Model BVT612010, Lot numbers: 9854121, 9868214, 9868311, 9875472, 9875632, 9876174, 9883295, 9884788, 9884951, 9886196, 9886312, 9932096, 9968511, 9974109, 9974126, 9976472, 9977091, 9978862, A002299, A002423. Model BVT312030, Lot numbers: 9854124, 9892081, 9941213, 9971096, 9971139, 9976506, 9977140, 9978964, 9979548, A003021, A003121, A003651, A007900, A008492, A008603, A008687.
Recalling Firm/ Manufacturer	Covidien 4600 Nathan Ln N Plymouth, Minnesota 55442-2890
For Additional Information Contact	Covidien Customer Service 800-716-6700
Manufacturer Reason for Recall	A manufacturing error resulted in the risk of incorrect proximal and distal balloon inflation port identification on the units. Units have been identified to have the distal balloon inflation port incorrectly labeled as proximal, and, the proximal balloon port incorrectly labeled as distal.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Mix-Up of Materials/Components
Action	Consignees were sent an Urgent Product Recall letter dated 12/15/2014. The letter described the issue, identified the affected product, and the required actions. Affected product was to be returned directly to customers' Covidien Sales Rep; or customers were to contact Covidien Service at 1-800-716-6700 to arrange for product return. Questions can be directed to the Covidien Sales Rep or to Covidien Service at 1-800-716-6700. Customers were to complete and return the Verification Form along with the unused product as soon as possible.
Quantity in Commerce	216 devices (207 US, 9 OUS)
Distribution	Worldwide Distribution - US Nationwide and the countries Australia, Canada, Finland, France, Germany, Ireland, Italy, Spain, Sweden, Switzerland, Turkey, and United Kingdom.

for Recall	port identification on the units. Units have been identified to have the distal balloon inflation port incorrectly labeled as proximal, and, the proximal balloon port incorrectly labeled as distal.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Mix-Up of Materials/Components
Action	Consignees were sent an Urgent Product Recall letter dated 12/15/2014. The letter described the issue, identified the affected product, and the required actions. Affected product was to be returned directly to customers' Covidien Sales Rep; or customers were to contact Covidien Service at 1-800-716-6700 to arrange for product return. Questions can be directed to the Covidien Sales Rep or to Covidien Service at 1-800-716-6700. Customers were to complete and return the Verification Form along with the unused product as soon as possible.
Quantity in Commerce	1032 devices (919 US, 113 OUS)
Distribution	Worldwide Distribution - US Nationwide and the countries Australia, Canada, Finland, France, Germany, Ireland, Italy, Spain, Sweden, Switzerland, Turkey, and United Kingdom.
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 = KRA and Original Applicant = COVIDIEN[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/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/cfPCD/classification.cfm
14. /scripts/cdrh/cfdocs/cfStandards/search.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfClia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=70048
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K130904

Class 1 Recall
Covidien Trellis 8 Peripheral Infusion System

See Related Information[22]

Date Posted	February 03, 2015
Recall Status[1]	Open
Recall Number	Z-1018-2015
Recall Event ID	70048[23]
Premarket Notification 510(K) Number	K130904[24]
Product Classification	Catheter, Continuous Flush[25] - **Product Code** KRA[26]
Product	Covidien Trellis-8 Peripheral Infusion System. Models CVT808015, CVT808025, CVT812015, and CVT812025. The following models are not offered for sale in the US: EVT808015, EVT808025, EVT812015, and EVT812025 Sterile EO. Product Usage: Intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.
Code Information	Model CVT808015, Lot numbers: 9895996, 9904675, 9910270, 9911926, 9912084, 9912200, 9922490, 9922584, 9922597, 9922601, 9922604, 9922606, 9922617, 9922620, 9922624, 9922635, 9923420, 9924840, 9928078, 9932274, 9933341, 9933774, 9933839, 9933934, 9934029, 9934440, 9934633, 9934686, 9936420, 9937544, 9937660, 9942679, 9943032, 9945436, 9948145, 9949409, 9950000, 9950703. Model CVT808025, Lot numbers: 9904237, 9906429, 9910270, 9912003, 9912117, 9912261, 9922644, 9922658, 9922661, 9922663, 9922739, 9922862, 9922868, 9923391, 9923401, 9923405, 9923428, 9923437, 9923454, 9924796, 9924802, 9924826, 9924847, 9924853, 9928334, 9928629, 9929004, 9929248, 9929344, 9933577, 9933797, 9933903, 9934553, 9934772, 9935134, 9935174, 9935241, 9935245, 9935471, 9935523, 9935757, 9935889, 9936140, 9936631, 9936680, 9936702, 9936735, 9937706, 9938500, 9938960, 9939918, 9939985, 9940234, 9940687, 9940916, 9948001, 9948544, 9949603, 9950150, 9950722, 9951391, 9952404, 9952785, 9952844, 9959913. Model CVT812015, Lot Numbers: 9904401, 9904676, 9910934, 9912387, 9922742, 9922793, 9922886, 9922892, 9922902, 9922904, 9922917, 9923224, 9923226, 9923237, 9923268, 9923275, 9923398, 9923446, 9923453, 9924832, 9932594, 9933474, 9933813, 9933924, 9934192, 9934730, 9936820, 9937095, 9937806, 9942701, 9943235, 9945140. Model CVT812025, Lot Numbers: 9910342, 9911492, 9911683, 9911812, 9912503, 9922498, 9922750, 9922753, 9922873, 9922911, 9923246, 9923403, 9923404, 9923409, 9923426, 9923442, 9923450, 9923457, 9924848, 9925351, 9933666, 9934311, 9934575, 9934700, 9935143, 9935199, 9935494, 9935636, 9935900, 9936109, 9936173, 9936570, 9936597, 9936848, 9937896, 9937968, 9938060, 9938219, 9938831, 9938896, 9941711, 9945304, 9947559, 9948088, 9949321, 9949934, 9950324, 9951247, 9951521, 9952927, 9957277, 9957530, 9959854, 9959944, 9960241, 9960324, 9960635, 9960807, 9961583, 9961682, 9962504, 9963558, 9964120, 9964347, 9964448, 9965066, 9965335, 9966329, 9966429, 9966999, 9967656, 9967694, 9968180, 9969396, 9972428, 9972429, 9972819, 9972867, 9972966.
Recalling Firm/ Manufacturer	Covidien 4600 Nathan Ln N Plymouth, Minnesota 55442-2890
For Additional Information Contact	Covidien Customer Service 800-716-6700
Manufacturer Reason	A manufacturing error resulted in the risk of incorrect proximal and distal balloon inflation