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Class 1 Device Recall Covidien Trellis 6 Peripheral Infusion System

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Class 1 Recall
Covidien Trellis 6 Peripheral Infusion System

Date Posted
February 03, 2015

Recall Status
Open

Recall Number
Z-1017-2015

Recall Event ID
70048

Premarket Notification
K071654

510(K) Number

Product Classification
Catheter, Continuous Flush - Product Code KRA

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, 9925678, 9932572, 9937308, 9937315, 9940474, 9940514, 9976340, 9976233, A001589, A001740.

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
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

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

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

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

Links on this page:

4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
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21. /scripts/cdrh/cfdocs/cfTPLC.inspect.cfm
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**

**Date Posted:** February 03, 2015  
**Recall Status:** Open  
**Recall Number:** Z-1018-2015  
**Recall Event ID:** 7004823  
**Premarket Notification 510(k) Number:** K13090424  
**Product Classification:** Catheter, Continuous Flush - Product Code KRA26  

**Product:** Covidien Trellis-8 Peripheral Infusion System. Models CTV808015, CTV808025, CTV812015, and CTV812025. 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 CTV808015, Lot numbers: 9865996, 9004675, 9910270, 9911926, 9912084, 9912200, 9922490, 9922584, 9922597, 9922601, 9922604, 9922606, 9922617, 9922620, 9922624, 9922635, 9923420, 9924840, 9928078, 9932274, 9933341, 9933374, 9933838, 9933934, 9934029, 9934440, 9934633, 9934683, 9936420, 9937544, 9937660, 9937678, 9943032, 9945436, 9948145, 9949409, 9950000, 9950703. Model CTV808025, Lot numbers: 9904237, 9905429, 9910270, 9912003, 9912117, 9912261, 9912264, 9922668, 9923391, 9923401, 9923403, 9923405, 9923428, 9923515, 9923545, 9924779, 9924802, 9924826, 9924847, 9924853, 9924833, 9924862, 9929204, 9929248, 9929344, 9933577, 9933797, 9933903, 9934553, 9934772, 9935184, 9935194, 9935521, 9935523, 9935675, 9935889, 9936140, 9936311, 9936860, 9936702, 9936735, 9937076, 9938550, 9938960, 9939918, 9939985, 9942701, 9943950, 9948454, 9949603, 9950150, 9950672, 9951619, 9951940, 9952785, 9952844, 9955913. Model CTV812015, Lot Numbers: 9904401, 9904676, 9910934, 9912387, 99222742, 99222793, 9922886, 9922892, 9922892, 9922904, 9922917, 9923224, 9923226, 9923237, 9923268, 9923275, 9923398, 9923446, 9923453, 9923602, 9932594, 9933474, 9933813, 9933824, 9934192, 9934730, 9936820, 9937095, 993806, 9942701, 9943423, 9945140. Model CTV812025, Lot Numbers: 9910342, 9911492, 9911683, 9911812, 9912503, 9922498, 9922750, 9922753, 9922873, 9922911, 9922946, 9923403, 9923404, 9923409, 9923426, 9923442, 9923450, 9923457, 9924848, 9924851, 9933666, 9933661, 9933670, 9933675, 9933677, 9933687, 9933688, 9933768, 9933796, 9933806, 9933821, 9933824, 9933831, 9933866, 9934111, 9941711, 9945304, 9947559, 9948088, 9949321, 9949439, 9951247, 9951521, 9952927, 9957277, 9957530, 9959854, 9959964, 9960241, 9965324, 9960635, 9960807, 9961583, 9961682, 9962504, 9963558, 9964120, 9964347, 9964488, 9965066, 9965335, 9966329, 9966429, 9966899, 9967566, 9967694, 9968180, 9968396, 9972428, 9972429, 9972819, 9972867, 9972966.

**Recalling Firm/Manufacturer:** Covidien  
For Additional Information Contact: Covidien Customer Service  
Manufacturer Reason: A manufacturing error resulted in the risk of incorrect proximal and distal balloon inflation.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=132204  
2/16/2015