Class 2 Device Recall Electrosurgical Cutting and Coagulation Device

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See Related Information[21]

Date Posted	February 21, 2014
Recall Status[1]	Open
Recall Number	Z-1069-2014
Recall Event ID	67193[22]
Premarket Notification 510(K) Number	K092789[23]
Product Classification	Laparoscope, General & Plastic Surgery[24] - **Product Code** GCJ[25]
Product	VirtuoSaph® Plus Endoscopic Vessel Harvesting System, Part number: VSP550, Sterile***Rx Only*** Product Usage: The VirtuoSaph Plus Endoscopic Vessel Harvesting System is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass.
Code Information	Lot numbers: 21K, 31K, 32K, 33K, 34K, 35K
Recalling Firm/ Manufacturer	Terumo Cardiovascular Systems Corporation 125 Blue Ball Rd Elkton, Maryland 21921-5315
For Additional Information Contact	Mary Swift 734-741-6056
Manufacturer Reason for Recall	Sterility of medical devices intended for use in surgical procedures may be compromised.
FDA Determined Cause [2]	PRODUCTION CONTROLS: Process Control
Action	Terumo CVS notified afected end users by phone on December 12, 2013 and advised that they had become aware that the sterile packaging barrier was breached in specific lots of VirtuoSaph® Plus Endoscopic Vessel Harvesting Systems. Customers were requested to return all unused affected product and verify that all users at their institution have been made aware of the risks associated with using the affected devices. For questions call 734-663-4145.
Quantity in Commerce	26 units
Distribution	USA Nationwide Distribution in the state of LA, NJ, and NY.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[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 = GCJ and Original Applicant = TERUMO CARDIOVASCULAR SYSTEMS CORP.[28]