**Class 2 Recall Electrocautery Device**

**Date Posted:** February 21, 2014  
**Recall Status:** Open  
**Recall Number:** Z-1069-2014  
**Recall Event ID:** 6719322  
**Premarket Notification 510(K) Number:** K09278923  
**Product Classification:** Laparoscope, General & Plastic Surgery, Product Code GCJ25  
**Product:** VirtuOSaph® Plus Endoscopic Vessel Harvesting System, Part number: VSP550, SterileRx Only**  
**Product Usage:** The VirtuOSaph Plus Endoscopic Vessel Harvesting System is intended 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  
**Address:** 125 Blue Ball Rd  
**City, State, Zip:** Elkton, Maryland 21921-5315  
**For Additional Information Contact:** Mary Swift  
**Phone:** 734-741-6068  
**Manufacturer Reason for Recall:** Sterility of medical devices intended for use in surgical procedures may be compromised.  
**FDA Determined Cause:** PRODUCTION CONTROLS: Process Control  
**Action:** Terumo CVS notified affected 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 Report26  

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 57.5527  
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

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http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=124916  
3/3/2014