

## **Terumo Coronary Ostia Cannula 10, 12, 14 Fr: Recall â€“ Fragments of Adhesive and Plastic in the Cannula Tip May Embolize**

U.S. Food & Drug Administration

**ISSUE:** Foreign fragments of adhesive and plastic in the cannula tip may embolize causing arterial injury, hemorrhaging or other serious events requiring unplanned surgery. Terumo Cardiovascular Systems Corporation (Terumo CVS) decided to remove the product line from the market and discontinue further supply.

**BACKGROUND:** The Terumo Coronary Ostia Cannula is indicated for use in delivering cardioplegia solution directly to the coronary arteries during cardiopulmonary bypass.

**RECOMMENDATION:** Terumo is advising customers to immediately discontinue use of any affected product and return all products in inventory.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm) [1]
- [Download form](#) [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[06/14/2011 - [Recall Notice](#) [3] - FDA]

[SOURCE](#) [4]

**Source URL (retrieved on 01/28/2015 - 3:30pm):**

[http://www.mdtmag.com/news/2011/06/terumo-coronary-ostia-cannula-10-12-14-fr-recall-%C3%A2%E2%82%AC%E2%80%9C-fragments-adhesive-and-plastic-cannula-tip-may-embolize?qt-most\\_popular=0](http://www.mdtmag.com/news/2011/06/terumo-coronary-ostia-cannula-10-12-14-fr-recall-%C3%A2%E2%82%AC%E2%80%9C-fragments-adhesive-and-plastic-cannula-tip-may-embolize?qt-most_popular=0)

### **Links:**

[1] <http://www.fda.gov/MedWatch/report.htm>

[2] <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>

[3] <http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm259062.htm>

[4] <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanM>

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[edicalProducts/ucm259082.htm](#)