Class 2 Device Recall Cordis EMPIRA RX PTCA Dilatation Catheter

Date Posted: June 11, 2014
Recall Status: Open
Recall Number: Z-1784-2014
Recall Event ID: 64273

Product: Cordis EMPIRA RX PTCA Dilatation Catheter Catalog # 85R30300S For cardiovascular use.
Code Information: Catalog # 85R30300S LOT # CEC0001447 exp date: 2014-08
Recalling Firm/Manufacturer: Cordis Corporation
14201 Nw 60th Ave
Miami Lakes, Florida 33014-2802

Manufacturer Reason for Recall: Dilatation catheters could exhibit radial versus axial tears should they burst during inflation.
Action: An Urgent Medical Device Recall letter and Acknowledgement form was sent overnight to multiple contacts in each account February 7, 2013. A representative will follow-up as necessary to facility obtaining signature, faxing the acknowledgment form to Cordis, collecting and returning units.
Quantity in Commerce: 80 units
Distribution: Worldwide distribution: US states: AZ, FL, IL, LA, MA, NJ, OR, SC, and TX. Armenia, Austria, Belgium, Colombia, Czech Republic, France, Hungary, Iran, Israel, India, Italy, Kuwait, Latvia, Lebanon, Luxembourg, Mexico, Morocco, Poland, Portugal, Russia, Saudi Arabia, South Africa, Spain, Switzerland, and United Arab Emirates.

Notes:
1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21, §57.55

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmfcfm
8. /scripts/cdrh/cfdocs/cfRL/cf.cfm
9. /scripts/cdrh/cfdocs/cfMADE/TextoSearch.cfm
10. /scripts/cdrhs/cfdocs/cfRES/res.cfm

6/16/2014