### Class 2 Device Recall Terumo Cardiovascular Systems

- **Date Initiated by Firm**: December 20, 2018
- **Create Date**: February 27, 2019
- **Recall Status**: Open, Classified
- **Recall Number**: Z-0966-2019
- **Recall Event ID**: 8201923
- **Product Classification**: Cardiovascular procedure kit - Product Code OEZ
- **Product**: Cardiovascular Procedure Kit (CLR MP4 COIL 2 SPIKE)
  - Catalog Number: 140222
- **Code Information**: Lot Numbers: V A30
- **Recalling Firm/Manufacturer**: Terumo Cardiovascular Systems Corporation
  - 125 Blue Ball Rd
  - Elkton MD 21921-5315
- **Manufacturer Reason for Recall**: Presence of natural rubber latex is not declared in the label
- **FDA Determined Cause**: Component design/selection
- **Action**: Terumo issued Urgent Medical Device Recall dated 12/20/18 stating reason for recall, health risk and an appropriate course of action for the return of affected product to Terumo.
  - Questions or concerns: Terumo CVS Customer Service. 1.800.521.2818 Monday - Friday, 8 a.m. - 6 p.m. ET.
- **Quantity in Commerce**: 12 packs
- **Distribution**: TX
- **Total Product Life Cycle**: [TPLC Device Report](#)

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1. A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#).
2. Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
3. The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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