### Class 2 Device Recall Level Sensor II Pads

**Date Initiated by Firm**  
February 20, 2017

**Create Date**  
March 14, 2017

**Recall Status**  
Open, Classified

**Recall Number**  
Z-1458-2017

**Recall Event ID**  
76459

**510(K)Number**  
K153376

**Product Classification**  
Console, heart-lung machine, cardiopulmonary bypass  
- Product Code DTO

**Product**  
Terumo Advanced Perfusion System 1-Level Sensor II Pads,

**Product Usage**  
Ultrasonic couplant used to facilitate the transmission of sound energy between the level sensor and the reservoir.

**Code Information**  

**Recalling Firm/Manufacturer**  
Terumo Cardiovascular Systems Corporation  
6200 Jackson Rd  
Ann Arbor MI 48103-9586

**For Additional Information Contact**  
Terumo CVS Customer Service  
800-521-2818

**Manufacturer Reason for Recall**  
Terumo CVS initiated a voluntary recall for the Level Sensor II Pads and Level Sensor Gel Pads due to non-compliant labeling because the product expiration date is displayed in a format that may not be recognizable to all users.

**FDA Determined Cause**  
Under Investigation by firm

**Action**  
Terumo CVS sent an Urgent Safety Advisory letter dated February 20, 2017 to customer. The letter identified the affected product problem and actions to be taken. For questions contact Terumo CVS at 1-800-521-2818.

**Quantity in Commerce**  
208,560

**Distribution**  
Worldwide Distribution - US Nationwide in the states of: AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MT, NC, NE, NJ, NM, NV, NY, OH, OK, PA, SC, TN, TX, UT, VA, WA, WI, WV and the countries of: Mexico, AUSTRALIA, UNITED ARAB EMIRATES (UAE), Indonesia, Singapore, Taiwan, Thailand, COLOMBIA, CHILE, Vietnam, India, China, Malaysia, BELGIUM, Japan, CANADA

**Total Product Life Cycle**  
TPLC Device Report

---

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA
Class 2 Device Recall Level Sensor II Gel Pads

Date Initiated by Firm: February 20, 2017
Create Date: March 14, 2017
Recall Status: Open, Classified
Recall Number: Z-1459-2017
Recall Event ID: 76456
510(K) Number: K153578

Product Classification: Console, heart-lung machine, cardiopulmonary bypass - Product Code DTQ

Product: Terumo Advanced Perfusion System 1-Level Sensor II Gel Pads

Product Usage: Level sensor pads are used to attach the level sensors to a hard shell reservoir, includes coupling gel.


Recalling Firm/Manufacturer: Terumo Cardiovascular Systems Corporation
Address: 6200 Jackson Rd
City: Ann Arbor
State: MI
Zip: 48103-9586

For Additional Information Contact: Terumo CVS Customer Service
Phone: 800-521-2818

Manufacturer Reason for Recall: Terumo CVS initiated a voluntary recall for the Level Sensor II Pads and Level Sensor Gel Pads due to non-compliant labeling because the product expiration date is displayed in a format that may not be recognizable to all users.

FDA Determined Cause: Under Investigation by firm

Action: Terumo CVS sent an Urgent Safety Advisory letter dated February 20, 2017 to customer. The letter identified the affected product problem and actions to be taken. For questions contact Terumo CVS at 1-800-521-2818.

Quantity in Commerce: 3,794

Distribution: Worldwide Distribution - US Nationwide in the states of: AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MT, NC, NE, NJ, NM, NV, NY, OH, OK, PA, SC, TN, TX, UT, VA, WA, WI, WV and the countries of: Mexico, AUSTRALIA, UNITED ARAB EMIRATES (UAE), Indonesia, Singapore, Taiwan, Thailand, COLOMBIA, CHILE, Vietnam, India, China, Malaysia, BELGIUM, Japan, CANADA.

Total Product Life Cycle: TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfdocs/cfelists/res.cfm?id=153247

4/3/2017