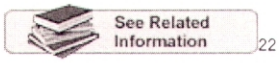
Class 2 Device Recall Level Sensor II Pads

See Related Information [22]

Date Initiated by Firm	February 20, 2017
Create Date	March 14, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1458-2017
Recall Event ID	76458[23]
510(K)Number	K153376[24]
Product Classification	Console, heart-lung machine, cardiopulmonary bypass[25] - **Product Code** DTQ[26]
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	Level Sensor II Pads, Catalog No. 195240, UDI No: 10886799001704, Lot Numers Ranging from 782300 through 817488, Manufactured from 20-Nov2015 to 25-Nov-2016; Distributed from 23-Nov-2015 through 15-Dec-2016.
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 [2]	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*[27]

[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



[22]

Date Initiated by Firm	February 20, 2017
Create Date	March 14, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1459-2017
Recall Event ID	76458[23]
510(K)Number	K153376[24]
Product Classification	Console, heart-lung machine, cardiopulmonary bypass[25] - **Product Code** DTQ[26]
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.
Code Information	Level Sensor II Gel Pads, Catalog No. 217390, UDI No: 00886799000519, Lot Numers Ranging from 782300 through 817488, Manufactured from 19-Nov-2015 to 25-Nov-2016; Distributed from 23-Nov-2015 through 15-Dec-2016.
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 [2]	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[27]

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