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Class 2 Device Recall Terumo Perfusion System



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Class 2 Device Recall Terumo Perfusion System



Date Initiated by Firm	May 23, 2008
Date Posted	November 07, 2008
Recall Status ¹	Terminated ³ on August 04, 2009
Recall Number	Z-0296-2009
Recall Event ID	49604 ²³
510(K)Number	K871131 ²⁴
Product Classification	Heart Lung Console ²⁵ - Product Code DTQ ²⁶
Product	<p>Terumo Sarns Level Sensor II (red) (Part # 195274) alarm level sensor transducer for use with Sarns Advanced Perfusion System I, Perfusion System 800 and Perfusion System 900; Terumo Cardiovascular Systems Corp., Ann Arbor, MI.; REF 195274. Level sensors are distributed as a finished device, as part of a kit, with a perfusion system 8000 safety monitor or with an Advanced Perfusion System 1 base.</p> <p>Level sensors are attached to the color coded connectors on the module and then to a hard-shell reservoir. Level detection is used to monitor blood levels in hard-shell reservoirs.</p>
Code Information	<p>Serial Numbers: 2264, 2281, 3077 through 3082, 3084 through 3088, 3092, 3094 through 3110, 3112 through 3115, 3117, 1932x, 1939x through 1943x, 1950x, 1951x, 1954x, 1973x, 1979x, 1980x, 1982x, 1990x, 1994x, 2000x, 2009x, 2014x through 2064x, 2066x through 2163x, 2194x through 2222x, 2225x through 2232x, 2280x, 2282x, 2283x, 2290x, 2294x, 2295x, 2298x through 2301x, 2303x, 2305x, 2306x, 2309x through 2311x, 2313x through 2315x, 2318x, 2319x, 2322x through 2324x, 2330x through 2332x, 2334x through 2347x, 2350x through 2467x, 2469x through 2471x, 2473x through 2503x, 2505x, 2507x through</p>

2529x, 2533x, 2536x, 2539x through 2541x, 2543x through 2551x, 2553x through 2572x, 2574x through 2583x, 2585x through 2609x and 2611x through 2624x.

Recalling Firm/ Manufacturer	Terumo Cardiovascular Systems Corporation 6200 Jackson Rd Ann Arbor MI 48103
For Additional Information Contact	800-262-3304
Manufacturer Reason for Recall	The level sensor may not properly couple to the reservoir, resulting in a sensor "not attached" message, an alert or alarm condition, or a failure to detect a low level condition.
FDA Determined Cause ²	Nonconforming Material/Component
Action	U.S. consignees were notified by (Urgent Medical Device Removal) letter dated 5/23/08 via FedEx and international affiliates were notified via e-mail on 5/27/08. Consignees were advised of the problem, and to continue using the affected sensors until replacements are available in late 2008. For questions or additional information, contact the Terumo CVS Customer Service at 1-800-521-2818.
Quantity in Commerce	547
Distribution	Worldwide including USA and countries of Australia, Belgium, Bolivia, Canada, Chile, Ecuador, Egypt, Honduras, Hong Kong, India, Indonesia, Japan, Jordan, Latin America, Malaysia, Panama, Philippines, Saudi Arabia, Singapore, South Africa, South Korea, Sri Lanka, Taiwan, Thailand, United Arab Emirates, Venezuela and Vietnam.
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 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](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)²⁹.

510(K) Database [510\(K\)s with Product Code = DTQ and Original Applicant = 3M HEALTH CARE, SARNS](#)³⁰

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