URGENT MEDICAL DEVICE RECALL

This is a voluntary URGENT MEDICAL DEVICE CORRECTION involving the repair or adjustment of the product without its physical removal to another location.

Attention:	**Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Risk Management**
CC:	**Chairman of Medical Board and all relevant Head(s) of Department**
Affected Product:	**Terumo® Advanced Perfusion System 1 – Power Manager Board**
Reference Number:	**AA-2018-004-C**
Effective Date:	**August 10, 2018**

REASON FOR RECALL

During internal testing, Terumo CVS identified that screws on a Terumo® Advanced Perfusion System 1 Power Manager Board (the base unit circuit board) were not torqued to specification. It is possible that a screw which is not properly torqued can loosen over time resulting in an electrical short.

The consequences of such failure can range from no impact on device performance to the potential for loss of critical system functionality.

Terumo CVS has determined that the issue originated with the Power Manager Board supplier. Because the supplier cannot confirm the torque specification, and out of an abundance of caution, Terumo CVS has identified potentially affected lots and is implementing field correction activities to ensure that all devices in the field function properly.

There have been no user complaints related to this issue.

POTENTIAL HAZARD

There have been no reported illnesses or injuries as a result of this issue.

Potential risks associated with Power Manager Board screws not being torqued properly and loosening with vibration over time include:

- Loss of power to the Central Control Monitor (CCM)
- Loss of power to the entire system
- Electrical arcing sound and/or burn smell/smoke emitting from the system
- Missed event notifications

NEXT STEPS

Review this Medical Device Correction and assure that all users have received notice of this issue.

A Terumo Field Service Representative will contact you to schedule the described field correction activities.

Terumo CVS recommends that you continue using your Terumo System 1 while waiting for this correction. If you have questions, contact Terumo CVS Customer Service:

800.521.2818

Customer Service Hours:
Monday – Friday
8 a.m. – 6 p.m. ET

CORRECTION

Terumo CVS is implementing field correction activities to ensure that the screws in potentially affected Terumo System 1 Power Manager Boards are properly torqued. A Terumo Field Service Representative will contact users to schedule the field correction activities. In addition, Terumo CVS is implementing corrective actions to mitigate future issues.

AFFECTED POPULATION

All patients undergoing cardiopulmonary bypass with the assistance of a Terumo System 1 which may contain a potentially affected Power Manager Board are at risk as a result of exposure to the defect or malfunction should it occur.

AFFECTED PRODUCT

Catalog Number	Product Description	Lot Number or Serial Number Range	Dates of Distribution
801763	Terumo System 1 Base -100/115V	See customized information on Customer Response Form included with this notice	29Jun2017 through 30May2018
801764	Terumo System 1 Base -220/240V		15Sep2017 through 18Apr2018

CUSTOMER INSTRUCTIONS

1. Review this Medical Device Correction and assure that all users have received notice of this issue.
2. Confirm receipt of this communication by completing and returning the attached Customer Response Form as indicated on the form.
3. Terumo CVS will contact users to schedule the field correction activities.

Note: Terumo CVS recommends that users continue using Terumo System 1 while waiting for this correction.

QUESTIONS?

We encourage you to contact Terumo CVS with any questions or concerns:

- **Terumo CVS Customer Service:** 1.800.521.2818, Monday – Friday, 8 a.m. – 6 p.m. ET
- **Recall Fax:** 1.734.741.6149

REPORTING

Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program:

- **Phone:** 1.800.FDA.1088
- **Fax:** 1.800.FDA.0178
- **Web:** www.fda.gov/medwatch/report.htm
  MedWatch Online Voluntary Reporting Form (mail to address on form): www.fda.gov/Safety/MedWatch/HowtoReport