URGENT MEDICAL DEVICE RECALL

This call is to notify you of an **URGENT MEDICAL DEVICE RECALL**. This recall is a Removal involving the physical removal of a device from its point of use to some other location for destruction.

Affected Product: **Flowmeter Module for the Terumo® Advanced Perfusion System 1**

Reference Number: **AA-2018-001-R**

Date of Phone Call: _____ ***Time:*** _____ ____ ***a.m.*** ___ ***p.m.***

Institution Name: _____

Contact Name: _____

Contact Title: _____

Contact Phone: _____ ***Contact Email:*** _____

AFFECTED PRODUCT

Catalog Number	Product Description	[redacted]	Dates of Distribution
802018	Flowmeter Module	[redacted]	October 17, 2017 – November 15, 2017

REASON FOR REMOVAL

Specific Flowmeter Modules for the Terumo Advanced Perfusion System 1 are being voluntarily recalled because a circuit board issue was detected during internal testing which may cause flow reading inaccuracies.

The conditions for the issue can change with each insertion of tubing into the Flow Probe. Therefore, the issue may only sometimes be present, and can change when tubing is removed or reinserted. Depending on the degree of inaccuracy, this issue may not be easy for the user to detect during setup or use (for example, following a Flow Probe relocation or manipulation).

Since the device failure may not be easily recognizable by the user, Terumo CVS is initiating a voluntary removal of the affected devices in the field.

POTENTIAL HAZARD

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

DRAFT

Inconsistent or inaccurate flow may generate and display confusing information on the Terumo System 1's Central Control Monitor or Centrifugal Control Unit. This could lead the clinician to make errors in patient treatment that could potentially result in patient hypo-perfusion or hyper-perfusion.

Once the inaccuracy is recognized by the user, if a replacement Flowmeter Module is available, replacement and reassignment of safety connections of the Flowmeter Module can be accomplished in less than 15 seconds. In the event that a replacement Flowmeter Module is not available, a less common mitigation is the use of a back-up stand-alone centrifugal pump or a stand-alone ultrasonic flowmeter system to provide flow data.

The likelihood of serious adverse health consequences is highly unlikely for all populations. The likelihood of medically reversible or transient adverse health consequences is highly unlikely for the overall population using the device and rare in the patient population at greatest risk.

CORRECTION

Terumo CVS determined that the circuit board issue was caused by an error in the supplier production assembly process of specific lots, and the issue has been corrected.

This communication is to alert you of this issue and to schedule an expedited service call for one of our Field Service Technicians to replace the affected Flowmeter Module with a corrected Flowmeter Module.

When necessary to avoid delaying or cancelling life-sustaining surgery, you can continue to use the Flowmeter Module while awaiting replacement.

AFFECTED POPULATION

All patients requiring cardiopulmonary bypass with the assistance of a Terumo System 1 with an affected Flowmeter Module.

CUSTOMER INSTRUCTIONS

You will receive a copy of this completed phone script by email along with a Customer Response Form. Please review the completed phone script, and complete and return the Response Form as indicated on the form.

Assure that all users have received notice of this issue, and prominently display this notice where all users may access it.

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

CONFIRMATION

Did I explain the situation to you clearly? _____YES _____NO

DRAFT

Do you have any additional questions?

_____

_____

_____

_____

_____

_____

Terumo Representative Name: _____

Terumo Representative Title: _____

Terumo Representative Signature: _____

Terumo Representative Phone No.: _____

DRAFT

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