May 1, 2017

VOLUNTARY MEDICAL DEVICE PRODUCT RECALL

Trima Accel® AUTOMATED BLOOD COLLECTION SYSTEM

Device Alert for Non-Recoverable Power Failure

Devices affected: New Trima Accel systems with serial numbers 1T07708- 1T08066

Dear Valued Customer,

The purpose of this letter is to communicate a potential non-recoverable power failure condition that could occur on the Trima Accel system and the actions that are being taken by Terumo BCT to address this potential failure.

REASON FOR THE VOLUNTARY ALERT

During routine manufacturing quality system testing, a Trima Accel device demonstrated a non-recoverable power failure. A subsequent investigation of the failure determined that a power filter cable, a component used in the internal electrical system, had a visible defect which caused the unit to lose power. Further evaluation determined that this defect may be present in other electrical cables which could cause a similar non-recoverable power failure. The cables have been isolated to specific manufacturing lots.

No other failures have been observed in manufacturing quality testing and there have been no customer reports of a non-recoverable power failure experienced in any Trima Accel system manufactured with the suspect cables.

RISK TO THE PATIENT

Users of the Trima Accel systems in the affected serial number bracket should be aware that there is a possibility the device could encounter a non-recoverable power failure.

If a power failure occurs prior to starting the procedure, the failure could result in the delay of the procedure until the device is repaired or another device is available.

If a power failure occurs after the procedure has begun, the procedure cannot be completed and automated Rinseback cannot be performed. Extracorporeal volume (ECV) varies dependant on the protocol chosen and procedural conditions. Maximum ECV for Trima Accel protocols where Platelet-Capable Tubing Sets are used is 196 mL and for RBC/Plasma is 182mL. Instructions to complete a manual Rinseback are outlined in the Trima Accel Automated Blood Collection System Operator's Manual. If Rinseback is not completed the physician should determine the impact to the patient and any intervention needed.

ACTIONS BEING TAKEN BY TERUMO BCT

Terumo BCT has worked with the supplier of the power filter cable to implement corrective and preventative actions. Terumo BCT is notifying customers that have devices manufactured between the dates 08/10/2016 to 01/11/2017, which may contain suspect cables. There is no information to conclude that a cable with the identified defect will cause a device failure once it has been installed, and no customer reports of this device failure have been received. However, in an abundance of caution, Terumo

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.
Europe, Middle East and Africa
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: +32.2.715.05.90
Fax: +32.2.721.07.70

Terumo BCT (Asia Pacific) Ltd.
89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261
Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A.
La Pampa 1517–12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Takanawa Park Tower 13F
20-14, 3-chome, Higashi Gotanda,
Shinagawa-ku, Tokyo 141-0022
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

BCT is taking action to replace the cables in all potentially affected Trima Accel systems. This voluntary action is limited to the Trima Accel system serial numbers listed above.

Your service representative will contact you to schedule a service visit. The replacement will take approximately 4 to 6 hours per device to complete.

ACTIONS REQUIRED BY HEALTHCARE PROVIDERS

1. Distribute this notification to all Trima Accel system users within your organization.
2. Continue to use your Trima Accel system in accordance with the operator's manual and the operator training materials.
3. **IMPORTANT**: Complete the attached acknowledgement and return it by fax or email to Terumo BCT by **07/31/2017**. **Your return of the acknowledgement is critical so that we can confirm that you have received the recall notice**.

CONTACT INFORMATION

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA in one of these ways:

- **Online**: http://www.fda.gov/Safety/MedWatch/HowtoReport/default.htm. A form is available to fax or mail.
- **By phone**: toll-free, 1.800.FDA.1088.

We appreciate your continued support and look forward to serving you. If you have any questions, please contact your Terumo BCT representative or your regional customer service center:

- U.S. Toll-Free: 1.877.3.FYI BCT (394 228)
- U.S.: +1.303.231.HELP (4357)
- Canada Toll-Free: 1.877.722.8411

Sincerely,

Charles Montgomery
Vice President, Global Product Quality

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.
Europe, Middle East and Africa
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: +32.2.715.05.90
Fax: +32.2.721.07.70

Terumo BCT (Asia Pacific) Ltd.
89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261
Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A.
La Pampa 1517–12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Takanawa Park Tower 13F
20-14, 3-chome, Higashi Gotanda,
Shinagawa-ku, Tokyo 141-0022
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800

TERUMOBCT

MEDICAL DEVICE RECALL RETURN RESPONSE

Trima Accel: Non-Recoverable Power Failure Alert

Acknowledgement and Receipt Form

Response Is Required

I have read and understand the recall instructions provided in the letter of May 1, 2017.

Yes ___ No ___

I have additional questions. I would like a Terumo BCT representative to contact me.

Yes ___ No ___

Are there any adverse events (serious injury or death) associated with a non-recoverable power failure that has not been previously reported? Yes ___ No___

If yes, please explain:

Facility Name: (Please print) _____

Facility Address: _____

City _____ State _____ Zip Code _____

Print Name/Title: _____

Signature: _____

Telephone: _____ E-mail address: _____

Please fax this completed form to 1.303.876.9277
or email it to Regulatory.Affairs@TerumoBCT.com

Terumo BCT, Inc.
10811 West Collins Ave.
Lakewood, Colorado 80215-4440
USA
USA Phone: 1.877.339.4228
Phone: +1.303.231.4357
Fax: +1.303.542.5215

Terumo BCT Europe N.V.
Europe, Middle East and Africa
Ikaroslaan 41
1930 Zaventem
Belgium
Phone: +32.2.715.05.90
Fax: +32.2.721.07.70

Terumo BCT (Asia Pacific) Ltd.
89 Science Park Drive
#04-25 (Lobby B)
The Rutherford
Singapore 118261
Phone: +65.6715.3778
Fax: +65.6774.1419

Terumo BCT Latin America S.A.
La Pampa 1517–12th Floor
C1428DZE
Buenos Aires
Argentina
Phone: +54.11.5530.5200
Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.
Takanawa Park Tower 13F
20-14, 3-chome, Higashi Gotanda,
Shinagawa-ku, Tokyo 141-0022
Japan
Phone: +81.3.6743.7890
Fax: +81.3.6743.9800