

May 1, 2017

**VOLUNTARY MEDICAL DEVICE PRODUCT RECALL**

**SPECTRA OPTIA® APHERESIS SYSTEM**  
**Device Alert for Non-recoverable Power Failure**

**Devices affected: Spectra Optia systems with serial numbers 1P04028 – 1P04392**

Dear Valued Customer,

The purpose of this letter is to communicate a potential non-recoverable power failure condition that could occur on specific Spectra Optia devices 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 Terumo BCT device that is similar to the Spectra Optia system 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.

Each Spectra Optia system also contains these cables. 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 Spectra Optia system manufactured with the suspect cables.

**RISK TO THE PATIENT**

Users of the Spectra Optia 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 any Spectra Optia protocol is 297mL during certain alarm conditions. Instructions to complete a manual Rinseback are outlined in the Spectra Optia Apheresis 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 cables to implement corrective and preventative actions. Terumo BCT is notifying customers that have devices manufactured between the dates 8/10/2016 to 1/11/2017, 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 BCT is taking action to replace the cables in all potentially affected Spectra Optia systems. This voluntary action is limited to the Spectra Optia system serial numbers listed above.

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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 Spectra Optia system users within your organization.
2. Continue to use your Spectra Optia 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**

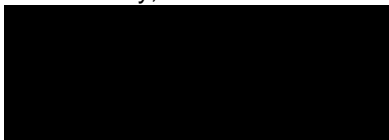
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA in one of these ways:

- **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

\*cc Chairman Medical Board and Relevant Head of Departments

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**MEDICAL DEVICE RECALL RETURN RESPONSE****Spectra Optia: 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 have 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](mailto:Regulatory.Affairs@TerumoBCT.com)**

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