TERUMOBCT

June 27, 2019

## VOLUNTARY MEDICAL DEVICE PRODUCT RECALL

**SPECTRA OPTIA® APHERESIS SYSTEM**

**Potential for Electronic Connection Intermittency**

**Devices Affected: Spectra Optia Apheresis Systems**

**Serial Numbers:** 1P00828, 1P00944, 1P01073, 1P01145, 1P01241, 1P01262, 1P01427, 1P01511, 1P01632, 1P01973, 1P02343, 1P03218, 1P03937, 1P05771, 1P06015, 1P06016, 1P06017, 1P06018, 1P06019, 1P06020, 1P06021, 1P06022, 1P06023, 1P06024, 1P06025, 1P06026, 1P06027, 1P06038, 1P06039, 1P06040, 1P06043, 1P06044, 1P06045, 1P06046, 1P06052, 1P06053, 1P06054, 1P06055, 1P06056, 1P06057, 1P06059, 1P06060, 1P06061, 1P06062, 1P06063, 1P06064, 1P06065, 1P06066, 1P06067, 1P06068, 1P06069, 1P06070, 1P06071, 1P06072, 1P06074, 1P06075, 1P06076, 1P06077, 1P06078, 1P06079, 1P06080, 1P06088, 1P06089, 1P06090, 1P06091, 1P06092, 1P06093, 1P06096, 1P06099, 1P06100, 1P06101, 1P06102, 1P06103, 1P06104, 1P06106, 1P06107, 1P06108, 1P06109, 1P06110, 1P06111, 1P06112, 1P06113, 1P06114, 1P06115, 1P06116, 1P06117, 1P06118, 1P06119, 1P06120, 1P06121, 1P06122, 1P06123, 1P06124, 1P06125, 1P06126, 1P06127, 1P06128, 1P06129, 1P06130, 1P06131, 1P06132, 1P06133, 1P06134, 1P06136, 1P06137, 1P06138, 1P06139, 1P06142, 1P06147, 1P06148, 1P06151, 1P06152, 1P06156, 1P06160, 1P06185, 1P06191

Dear Valued Customer:

Terumo BCT has become aware of an unintended height deviation of the physical supports for a circuit card assembly (CCA) installed in the Spectra Optia apheresis device. Spectra Optia apheresis systems contained in the serial numbers listed above could exhibit an intermittent electronic connection due to this deviation.

**REASON FOR PRODUCT RECALL**

Terumo BCT has **not** received any customer reports of intermittent electronic connections that were identified to have been caused by this identified defect. Terumo BCT is issuing this recall and corrective action notice to inform users of the Spectra Optia system about this defect and to assure them that all potentially affected devices are corrected. You are being notified of this defect because our records indicate that you may have received one or more of the identified devices.

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## RISK TO THE PATIENT

This notice advises Spectra Optia operators to observe and adhere to all system alarms and their resulting on-screen instructions by following good clinical practice.

- No unsafe system behavior has been linked to this deviation.
- All alarms contain on-screen instructions; please follow them accordingly.
- If the system presents repeated alarms across multiple procedures that do not result from a known cause, it may be necessary to end the procedure.

## ACTIONS BEING TAKEN BY TERUMO BCT

a) Terumo BCT is taking action by notifying you of this potential defect in a Spectra Optia device you have from the above identified list.

b) In addition to this letter, Terumo BCT will arrange for inspection of all Spectra Optia apheresis systems with the CCA card assembly supports that potentially contain this identified defect. A member of Terumo BCT's technical service team will contact you to arrange for inspection of any potentially affected devices at your facility. Any identified devices containing-this defect will be corrected by replacing the housing that contains the CCA card assembly supports. Devices that are not affected will not require correction.

## ACTIONS REQUIRED BY HEALTHCARE PROVIDERS AND DISTRIBUTORS

1. Distribute this notification to all Spectra Optia system users within your organization.
2. Continue to use your Spectra Optia system(s) in accordance with the operator's manual and the operator training materials.
3. If any Spectra Optia system(s) present repeated alarms across multiple procedures that do not result from a known cause, it may be necessary to end the procedure.

   **IMPORTANT**: Complete the attached acknowledgement and fax or email the acknowledgement to Terumo BCT by **August 9th, 2019**. Your return of the acknowledgement is critical so that we can confirm that you have received the Safety Alert.

## CONTACT INFORMATION

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

- Online: http://www.fda.gov/Safety/MedWatch/HowtoReport/default.htm. Complete the form provided and return it by fax or mail.
- Phone U.S. Toll-Free: 1.800.FDA.1088

Terumo BCT is dedicated to providing you with the highest quality support and communicating information regarding our products. If you have any questions, please contact your Terumo BCT representative or your regional Customer Support 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,

Cynthia A Hougum, PhD
Senior Vice President, Global Quality Transformation

TERUMOBCT

## VOLUNTARY MEDICAL DEVICE PRODUCT RECALL RETURN RESPONSE

### Spectra Optia System: Potential for Electronic Connection Intermittency

### Acknowledgement and Receipt Form

### Response Is Required

I have read and understand the recall instructions provided in the letter of June 27, 2019.

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 electronic connection intermittency on Spectra Optia 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: _____ Email Address: _____

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