TERUMOBCT

16 April 2018

VOLUNTARY MEDICAL DEVICE SAFETY ALERT

SPECTRA OPTIA® APHERESIS SYSTEM

Reminder to Prime Blood Warmers

Devices Affected: All Spectra Optia Apheresis Systems

Dear Valued Customer:

This letter has two purposes:

1) To remind Spectra Optia system users of this potential safety hazard: If a blood warmer is attached to a Spectra Optia tubing set and the blood warmer is not primed before use, air could be delivered to a patient.
2) To reinforce the actions required to mitigate this risk.

Many Spectra Optia procedures include the option to use a blood warmer. The Spectra Optia operator's manual instructs operators how to connect and prime a blood warmer when one is used. The operator's manual also includes warnings about the risk of delivering air to a patient if a blood warmer is not primed. These warnings appear throughout the manual: 1) in the "General procedural warnings" section in the Preface of the operator's manual, and 2) in the instructions for priming the lines before connecting the patient for each procedure for which a blood warmer is an option.

If an operator did not observe this warning and/or did not follow the instructions in the operator's manual, this safety hazard could occur.

REASON FOR THE SAFETY ALERT

Terumo BCT has **not** received any customer reports of air being returned to patients due to an unprimed blood warmer. A blood warmer that is connected between the Spectra Optia tubing set return line and the patient and that is not primed could cause a risk.

A blood warmer can be attached to the tubing set either at the beginning of a procedure or during a procedure.

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- **Scenario 1**: **The operator attaches a blood warmer to the return line at the beginning of the procedure.** In this scenario, the operator sees the screen shown in Figure 1. The text and graphics instruct the operator to connect the blood warmer. The text that instructs the operator to prime the blood warmer is circled for illustration purposes in Figure 1.

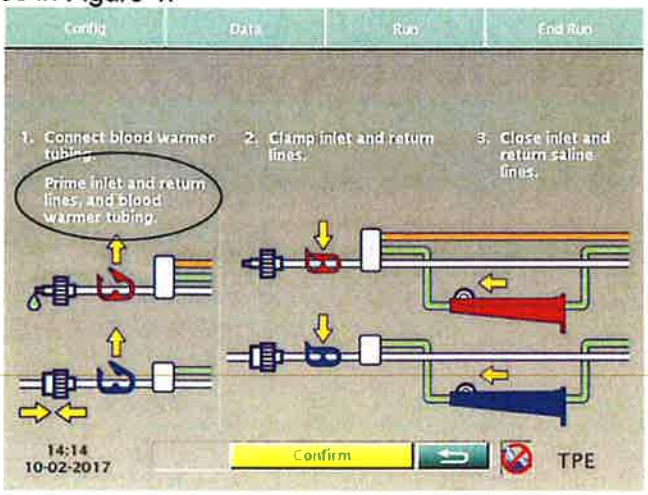

Figure 1: Screen instructs the operator to prime the blood warmer tubing

- **Scenario 2: The operator connects a blood warmer to the return line in the latter stages of system prime but before the patient is connected OR the operator connects a blood warmer to the return line mid-procedure.** In this scenario, the text that instructs the operator to connect the blood warmer and to prime the blood warmer tubing does not appear, as shown in Figure 2.

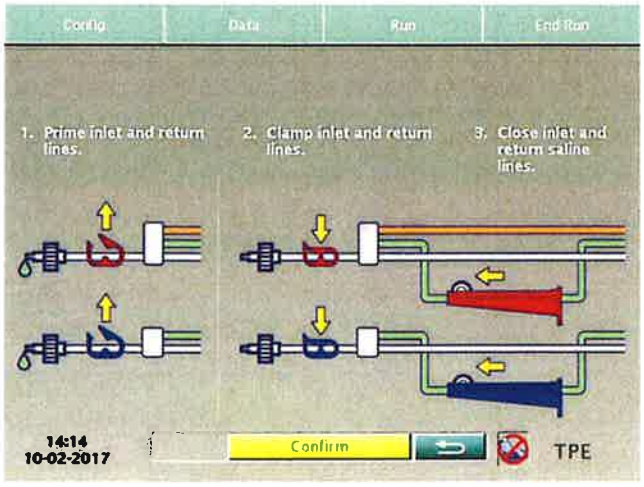

Figure 2: Screen does not instruct the operator to prime the blood warmer tubing

If an operator connects a blood warmer mid-run but fails to prime the blood warmer tubing set and continues to connect the patient and resumes the procedure, any air in the blood warmer tubing set will be returned to the patient.

RISK TO THE PATIENT

If the operator fails to prime the blood warmer tubing set before connecting the patient and beginning or resuming the procedure, air will be returned to the patient. The volume of air that could be infused depends upon the size and type of blood warmer. This notice advises Spectra Optia operators to follow good clinical practice:

- After connecting a blood warmer to the Spectra Optia tubing set, prime the blood warmer before connecting a line to the patient and beginning or resuming a procedure.
- Visually inspect the blood warmer to ensure proper priming of any set before you begin or resume any procedure to minimize the risk of air being infused to the patient.

ACTIONS BEING TAKEN BY TERUMO BCT

Terumo BCT is taking action by notifying you that a system reminder to prime a blood warmer may not always be provided in screen instructions.

In addition to this letter, operator instructions have been enhanced, and a copy of these enhanced instructions are included in Attachment 1 with this notice. Please review the attachment and keep a copy with each Spectra Optia operator's manual at your facility.

Again, there have been no reports of air having been delivered to a patient because a blood warmer was not properly primed.

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. See Attachment 1, Figures 1 and 2. When you configure the use of a blood warmer for the tubing set return line, the instructions to connect the blood warmer are displayed on the screen before you connect the patient. **You must prime the blood warmer tubing set before you connect the patient.**

4. See Attachment 1, Figures 3 and 4. In Chapter 6, the "Selecting Procedure Options" section of the operator's manual, follow the updated instructions to indicate the use of a blood warmer during the procedure. **You must prime the blood warmer tubing set before you connect the patient.**

5. **IMPORTANT**: Complete the attached acknowledgement and fax or email the acknowledgement to Terumo BCT by **31 MAY 2018**. 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,

Charles Montgomery
Vice President, Global Quality

TERUMOBCT

MEDICAL DEVICE SAFETY ALERT RETURN RESPONSE

Spectra Optia: Reminder to Prime Blood Warmers

Acknowledgement and Receipt Form

Response Is Required

I have read and understand the recall instructions provided in the letter of 16 April 2018.

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 failure to prime a blood warmer tubing set 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.

ATTACHMENT 1

Keep a copy of this attachment with each Spectra Optia operator's manual at your facility.

The following information appears in the Spectra Optia system operator's manual, Chapter 4, section "Configuring the Use of a Blood Warmer."

Tab	Parameter	Description	Setting Options
Blood Warmer	Return line	Indication that a blood warmer will be connected to the return line. Instructions to connect the blood warmer tubing set are displayed on the screen before you connect the patient.	• Yes • No Default: No

Figure 1: Current Spectra Optia system operator's manual instructions

Tab	Parameter	Description	Setting Options
Blood Warmer	Return line	Indication that a blood warmer will be connected to the return line. You must prime the blood warmer tubing set before you connect the patient.	• Yes • No Default: No

Figure 2: Updated instructions

The following information appears in the Spectra Optia system operator's manual, Chapter 6.

Indicating the Use of a Blood Warmer

Follow the instructions below to indicate the use of a blood warmer during the procedure. To connect and prime the blood warmer tubing, follow the instructions on the screen. If you are using a blood warmer on the replace line, refer to "Exchange Procedures: Using a Blood Warmer on the Replace Line" on page (*page number varies*).

Figure 3: Current Spectra Optia operator's manual instructions

Indicating the Use of a Blood Warmer

Follow the instructions below to indicate the use of a blood warmer during the procedure. You must prime the blood warmer tubing set before you connect the patient. If you are using a blood warmer on the replace line, refer to "Exchange Procedures: Using a Blood Warmer on the Replace Line" on page (*page number varies*).

Figure 4: Updated instructions