December 2020

FSN Ref: Spectra Optia FA38 FSCA Ref: Spectra Optia FA38

Urgent Field Safety Notice
Clarification for Performing a Custom Prime With Red Blood Cells

For Attention of*:All Spectra Optia Apheresis System Users

Contact details of local representative (name, e-mail, telephone, address etc.)*
Terumo BCT Europe NV, Ikaroslaan 41B-1930, Zaventem, Belgium

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Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	All Spectra Optia Apheresis Systems and All Protocols
1.	2. Commercial name(s)
	SPECTRA OPTIA® APHERESIS SYSTEM
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	Apheresis
1.	5. Device Model/Catalogue/part number(s)*
	61000
1.	6. Software version
1.	7. Affected serial or lot number range
	All serial numbers.
1.	8. Associated devices

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	None. Product is performing as intended.
2.	2. Hazard giving rise to the FSCA*
	Terumo Blood and Cell Technologies has received complaints from three customers of adverse events during continuous mononuclear cell collection (CMNC) procedures when the RBC unit used for the custom prime was diluted to a Hematocrit of less than 30%. These adverse events occurred because of a reduction in the patient's RBC that included exacerbation of anemia.
2.	3. Probability of problem arising
	0.0938%
2.	4. Predicted risk to patient/users
	If the operator performs a custom prime with a diluted RBC unit that results in insufficient RBC in the system prior to connecting the patient, an unintended decrease in patient Hct may occur. It is the responsibility of the treating physician to assess the patient's condition and determine the tolerance of the patient to ECV and RCV shifts.
2.	5. Further information to help characterise the problem
2.	6. Background on Issue
	Terumo Blood and Cell Technologies is issuing this letter in response to reports of adverse events related to performing a custom prime with an insufficient number of red blood cells (e.g., diluted RBC units) on low-TBV patients. This letter has two purposes: 1. To inform customers performing a custom prime using red blood cells of the importance of ensuring that the custom prime unit contains enough red blood

	cells (RBC) or RBC volume (RCV) to adequately fill the extracorporeal circuit of the tubing set. An insufficient RCV may lead to an unintended decrease in patient hematocrit (Hct). This issue may occur due to the use of low-volume and/or diluted custom prime RBC units. 2. To provide additional information to mitigate the risk of using diluted and/or low-volume RBC custom prime units. The function of a custom prime is to displace the prime saline in the tubing set with donor RBC, plasma, or albumin prior to connecting a patient so that the patient remains isovolemic throughout a procedure. In addition, a certain extracorporeal circuit volume (ECV) and RCV are required in the tubing set to establish and maintain the interface during the procedure. The ECV and RCV required vary and depend on the tubing set, the type of filler used, whether a blood warmer is used on the return line, and the entered patient total blood volume (TBV) and hematocrit (Hct). At the start of a procedure, the system draws in the ECV and RCV necessary, first from the custom prime unit and then from the patient, if necessary, to fill the tubing set and establish the interface. If the custom prime unit used does not contain enough RBC to adequately fill the set (e.g., if it is diluted or low-volume), the additional RCV the system needs will be pulled from the patient. As a result, the patient will experience a decrease in Hct and may be unable to tolerate the procedure.
2.	7. Other information relevant to FSCA
	See attachments

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	Complete the attached acknowledgement and fax or email the acknowledgement to Terumo Blood and Cell Technologies by December 31, 2020. Your return of the acknowledgement is critical so we can confirm that you have received the Safety Alert.
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

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<table>
<tr><td>3.</td><td colspan="3">5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None

1. This safety alert serves to inform you of the potential risk of using a diluted or low-volume RBC unit when performing a custom prime with red blood cells.
2. In addition to this alert, Attachment 1 provides enhanced operator instructions. Please review the attachment and keep a copy with each Spectra Optia operator’s manual at your facility.
3. Additional supplemental training specific to performing a custom prime has also been released. This training is currently available in eLearning format in English at www.terumobct.com/elearning under Spectra Optia Apheresis System titled “Spectra Optia Custom Prime eLearning Course.”</td></tr>
<tr><td>3</td><td>6. By when should the action be completed?</td><td colspan="2">Complete the attached acknowledgement and fax or email the acknowledgement to Terumo Blood and Cell Technologies by December 31, 2020. Your return of the acknowledgement is critical so we can confirm that you have received the Safety Alert.</td></tr>
<tr><td>3.</td><td colspan="2">7. Is the FSN required to be communicated to the patient /lay user?</td><td>No</td></tr>
<tr><td>3</td><td colspan="3">8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</td></tr>
<tr><td></td><td colspan="3"></td></tr>
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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	**3.** For Updated FSN, key new information as follows:	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Terumo BCT, Inc.
	b. Address	10811 W. Collins Ave. Lakewood CO 80215 USA
	c. Website address	www.terumobct.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	1. Customer letter containing Procedural Considerations 2. FSN Customer Reply Form
4.	10. Name/Signature	

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.