January 2020

FSN Ref: Spectra Optia FA33 FSCA Ref: Spectra Optia FA33

Urgent Field Safety Notice
Spectra Optia procedures with Correct Connect ACD-A Solution

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

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

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Urgent Field Safety Notice (FSN)
Spectra Optia procedures with Correct Connect ACD-A Solution
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Spectra Optia Apheresis Tubing sets and anticoagulant solutions with the CORRECT CONNECT Anticoagulant connector
1.	2. Commercial name(s)
	See 5
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Apheresis
1.	5. Device Model/Catalogue/part number(s)*
	40814 (Anticoagulant Citrate Dextrose Solution, ACD-A 500mL EMEA), 40818 (Anticoagulant Citrate Dextrose Solution, ACD-A 750mL EMEA), 12120 (Spectra Optia Collection Set), 12220 (Spectra Optia Exchange Set), 12320 (Spectra Optia IDL Set)
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	All lot numbers.
1.	8. Associated devices
	Spectra Optia System.

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 BCT has received reports of users failing to break the frangible on the ACD-A bag when connecting a second bag of ACD-A even though the IFU and other instructions and training contain this information.
2.	3. Probability of problem arising
	0.004%
2.	4. Predicted risk to patient/users
	An inadequately broken or unbroken frangible can lead to underdelivery of anticoagulant and clotting in the extracorporeal circuit with loss of collected product and the need to do an additional MNC or CMNC procedure. In a WBCD or PLTD procedure it can lead to inadequate therapy. In TPE and RBCX procedures, the risks are reduced due to the failure occurring late in the procedure. The Hazard/Risk index is in the Low category
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	In July 2017 Terumo BCT has introduced a new, non-proprietary connector for Anticoagulant solutions used with donor and therapeutic apheresis devices. This new connector, called CORRECT CONNECT, is designed to reduce the potential for accidental misconnections of the solution lines. Terumo BCT has distributed a letter, a

	brochure and a Quick Reference Guide to all Spectra Optia users. Terumo BCT representatives have also trained users on how to use the Correct Connect® system.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	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 Take note of the importance of breaking the frangible on the ACD-A bag and of the expected consequences of a failure to break the frangible such as clotting, potential loss of product and delayed therapy. Details are already contained in IFU and Quick Reference Guide.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Terumo BCT is reminding users of the importance of breaking the frangible on the ACD-A bag and of the expected consequences of a failure to break the frangible such as clotting, potential loss of product and delayed therapy. Details are already contained in IFU and Quick Reference Guide.	
3	6. By when should the action be completed?	Terumo BCT anticipates delivering the FSN letter to UK customers by 15 September 2019.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
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?	

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	Choose an item. Choose an item.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
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:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Insert Name and Title here and signature below

	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.