August 2023

FSN Ref: T-PAS+ FA51 FSCA Ref: T-PAS+ FA51

Urgent Field Safety Notice

Safety Alert Regarding Oil Residue on Luer Connectors of Terumo Platelet Additive Solution+ (T-PAS+)

For Attention of*:All Terumo Platelet Additive Solution+ 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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Safety Alert Regarding Oil Residue on Luer Connectors of Terumo Platelet Additive Solution+ (T-PAS+)

Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Terumo Platelet Additive Solution+ (T-PAS+)
1.	2. Commercial name(s)
	Terumo Platelet Additive Solution+ (T-PAS+)
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	The T-PAS+ solution is a platelet additive solution intended to partially replace plasma in the preparation and storage of a buffy coat-derived platelet concentrate or apheresis platelet unit.
1.	5. Device Model/Catalogue/part number(s)*
	40853, 40855, 40856
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	C/N 40853 - 23052020, 23052021 C/N 40855 - 23054013, 23054014 C/N 40856 - 23055009
1.	8. Associated devices

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The T-PAS+ lots listed above may contain oil residue on the luer connectors used to mix additive solution with collected platelet products, including the frangible connector that is in direct contact with the additive solution.
2.	2. Hazard giving rise to the FSCA*
	There is a possibility that this oil residue may transfer into the fluid pathway of the additive solution and into the final collected product. This residue has been identified as Renolin B 15 VG 46, which is not intended for use in medical applications.
2.	3. Probability of problem arising
	Terumo Blood and Cell Technologies has received no reports of adverse events or injuries related to the presence of oil residue on T-PAS+ products.
2.	4. Predicted risk to patient/users
	There is potential for adverse consequence due to pulmonary oil microembolism (POME) in the population at greatest risk in the event the residue transfers into a platelet product and is subsequently transfused. The population at greatest risk is defined as neonates, paediatrics, critically ill patients, and those with impaired lung function. In the general

	population, this potential degree of oil residue is not likely to cause an adverse health consequence.
2.	5. Further information to help characterise the problem
	Renolin B15 VG 46 is an industrial-grade, mineral-based demulsifying hydraulic oil. Review of the Safety Data Sheet for Renolin B 15 VG 46 and its components indicates that the substance has a low risk for toxicity and has not been classified as a carcinogen or deemed hazardous.
2.	6. Background on Issue
2.	7. Other information relevant to 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	
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 November 30, 2023. Your return of the acknowledgement is critical so we can confirm that you have received the information.
3.	3. Particular considerations for: Choose an item. 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
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None 1. We are notifying you of this potential issue on the T-PAS+ luer connector as described above and are instructing customers to discontinue use of any affected product. 2. A Supplier Corrective Action has been issued to the luer connector vendor. 3. We are actively investigating corrective actions to prevent future errors of this type.	

3.	6. By when should the action be completed?	Complete the attached acknowledgement and fax or email the acknowledgement to Terumo Blood and Cell Technologies by November 30, 2023. Your return of the acknowledgement is critical so we can confirm that you have received the Safety Alert.
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?	

	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:	
	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:	
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. FSN Customer Reply Form
4.	10. Name/Signature	[redacted] **Vigilance System Coordinator** [redacted]

	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.

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	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.