Rev 1: September 2018

FSN Ref: FSN_01_2022_DK FSCA Ref: FSCA_01_2022

Date: 26-04-2022

Urgent Field Safety Notice
Volumed Set – APTPK0J-PP

For Attention of*:

Contact details of local representative (name, e-mail, telephone, address etc.)*
Timik Group AB, Box 426, SE-19124 Sollentuna, Sweden. Contact: mats.nilsson@timikgroup.com

Rev 1: September 2018

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Urgent Field Safety Notice (FSN)
Volumed Set – APTPK0J-PP
Tube disconnection from drip chamber – blood leakage

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Volumed Transfusion Set, Non-Vented, Polypropylene, 235cm, Robson Clamp and Male Luer Lock
1.	2. Commercial name(s)
	Volumed ® Set
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	Set for blood Transfusion
1.	5. Device Model/Catalogue/part number(s)*
	APTPK0J-PP
1.	6. Software version
	n.a.
1.	7. Affected serial or lot number range
	21PH088 21PH202 21PH210
1.	8. Associated devices
	n.a.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	End user experienced case of disconnection between the drip chamber and the tubing.
2.	2. Hazard giving rise to the FSCA*
	Blood can come into contact with the skin of healthcare workers and patients. Failure to perform the transfusion. Delay in the transfusion.
2.	3. Probability of problem arising
	Low
2.	4. Predicted risk to patient/users
	Blood contamination
2.	5. Further information to help characterise the problem
	none
2.	6. Background on Issue
	Internal analysis has shown that the connection between tube and drip chamber may come loose during normal usage due to impredictable tensile stress from user manipulation.
2.	7. Other information relevant to FSCA
	none

	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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	immediately
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? NO Devices that are not defective and therefore did not become disconnected during use, have fulfilled their intended use, i.e. to perform the transfusion correctly	
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 modification of the components of the products in order to guarantee a more secure connection	
3	6. By when should the action be completed?	Specify where critical to patient/end user safety
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?	
	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	**Phoenix srl**
	b. Address	**Via Leonardo da Vinci 55, san Felice sul Panaro (MO), Italy**
	c. Website address	Only necessary if not evident on letter-head.
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	**Federico Prandini** 

	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.