Rev 1: September 2018
FSN Ref: 01/2020 FSCA Ref: 01/2020

Date: 20/01/2020

Urgent Field Safety Notice
APTPK0J

For Attention of*:

[redacted]

Contact details of local representative (name, e-mail, telephone, address etc.)*
Marco Bulgarelli; Phoenix s.r.l.; info@phoenixbiomed.it; +39 0535 20085; via Leonardo da Vinci 55, San Felice sul Panaro,

Rev 1: September 2018
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Urgent Field Safety Notice (FSN)
APTPK0J
Infection – Late delivery of Blood Solution

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Volumed Transfusion Set, Non-Vented, DEHP-Free PVC, 235cm, Robson Clamp and Male Luer Lock. Sterile Item for Single Use
1.	2. Commercial name(s)
	Volumed® Set
1.	3. Unique Device Identifier(s) (UDI-DI)
	n/a
1.	4. Primary clinical purpose of device(s)*
	Set For Infusion
1.	5. Device Model/Catalogue/part number(s)*
	APTPK0J
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	Batch 19PH427
1.	8. Associated devices
	n/a

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	End user experienced one isolated case of disconnection (between drip chamber and tubing). Recall of the batch is requested due investigation of the causes by the manufacturer
2.	2. Hazard giving rise to the FSCA*
	Possible Infection – late delivery of blood solution
2.	3. Probability of problem arising
	Very low. One isolated event: item is on the market since 2015 (different batches)
2.	4. Predicted risk to patient/users
	n/a
2.	5. Further information to help characterise the problem
	n/a
2.	6. Background on Issue
	n/a
2.	7. Other information relevant to FSCA
	n/a

	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?	n/a
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
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	**20 february 2020**
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? n/a	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	n/a
4.	**3.** For Updated FSN, key new information as follows:	
	n/a	
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:	
	n/a	
4	6. Anticipated timescale for follow-up FSN	n/a
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Phoenix s.r.l.**
	b. Address	**Via Leonardo da Vinci 55, San Felice sul Panaro, 41038, Modena, Italy**
	c. Website address	**/**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * **Yes**	
4.	9. List of attachments/appendices:	**/**
4.	10. Name/Signature	**Marco Bulgarelli – Consumables Manager**

	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.

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM
PRODUCT FIELD ACTION BY PHOENIX S.R.L. – IMMEDIATE ATTENTION REQUIRED

Ref.: 01/2020

RETURN COMPLETED FORM IMMEDIATELY TO:

E-Mail: Simon Neukom **simon.neukom@arcomed.com**

❑ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action.	❑ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm our inventory DOES include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned.

Ref. Code	Batch Number	Qty. returned
APTPK0J	**19PH427**	

Complete this Acknowledgement form and return immediately by using e-Mail address above.

Institution Name (name of hospital, healthcare organization)	
Institution Adress	**Phone / eMail**
Form Completed by	**Date**
Signature:	