Rev 1: September 2018

FSN Ref: FSN_01_2023 FSCA Ref: FSCA_01_2023

Date: 27/03/2023

Urgent Field Safety Notice
Volume Silicone Set – APSPK0J

For Attention of*: Hospitals, Healthcare Professionals

Contact details of local representative (name, e-mail, telephone, address etc.)*
Arcomed AG Steinackerstrasse 29, 8302 Kloten T 00 41 4338 890 30 T 00 44 1268 5445 80 info@arcomed.com qm@arcomed.com

Urgent Field Safety Notice (FSN)
Volume Silicone Set – APSPK0J

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Volumed Set, Light Protect Polypropylene Tubing, 280cm, Robson Clamp and Male Luer Lock
1.	2. Commercial name(s)
	Volumed ® Silicone Set
1.	3. Unique Device Identifier(s) (UDI-DI)
	NA
1.	4. Primary clinical purpose of device(s)*
	Infusion set
1.	5. Device Model/Catalogue/part number(s)*
	APSPK0J
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	21PH822
1.	8. Associated devices
	NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Discrepancy between production lot and lot on the primary packaging labelling for code APSPK0J lot 21PH822.The labelling of the primary packaging incorrectly shows lot 21PH882
	 Photo of what the primary labelling of the affected product looks like: lot 21PH882 is wrong. Correct lot number is 21PH822.
	2. Hazard giving rise to the FSCA*

2.	None. The problem is not related to safety and performance aspects of the device. The aim of the field safety notice is to inform the hospitals of the action to be taken in order to guarantee the right traceability of the product inside the hospital.
2.	3. Probability of problem arising
	Very low. This is the only case registered.
2.	4. Predicted risk to patient/users
	None
2.	5. Further information to help characterise the problem
	None
2.	6. Background on Issue
	As a result of market surveillance activities, Phoenix was informed of the discrepancy in the information relating to the APSPK0J lot code 21PH822. It was found that the primary packaging of the product incorrectly listed lot 21PH882. Phoenix has verified through its traceability records that the correct lot code is 21PH822 and that the error therefore relates to the creation of the primary packaging label (laminated paper blister + plastic film)
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

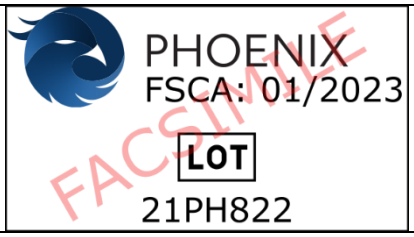
☒ On-site device modification/inspection

☐ Follow patient management recommendations

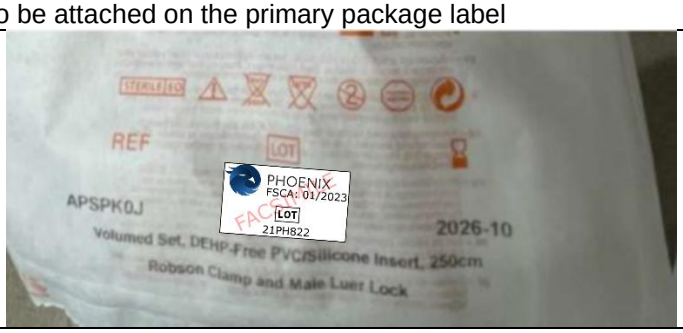
☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Phoenix srl, through its distributor Arcomed AG, will provide labels, such as the one shown in the example, to be attached above the wrong batch number.



Example of label to be attached on the primary package label



Example of how to attached the label on the packaging.

3.	2. By when should the action be completed?	As soon as possible.
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 Phoenix srl will provide the stickers with the correct lot number and identification of the FSCA in order to keep track of the action.	
3	6. By when should the action be completed?	Phoenix srl, through distributor arcomed ag, will send labels to hospitals at the same time as the FSN is sent out. The replacement label should be affixed as soon as possible
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.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	**3.** For Updated FSN, key new information as follows:	
	NA	
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:	
	NA	
4	6. Anticipated timescale for follow-up FSN	NA
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	NA
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	**FSN_01_2023_acknowledgement _form**
4.	10. Name/Signature	**Federico Prandini** **RA 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.