Rev 1: December 9th 2021
FSN Ref: FSN_0001_Osypka_ FSCA _CAPA_117_2021
FSCA Ref: FSCA_0001_CAPA_117_2021

Date: 09.12.2021

Urgent Field Safety Notice (FSN)

VACSII 22x40 Cardiac valvuloplasty catheter

For Attention of: Cardio Vascular and Purchasing Department

Dear business partner

We have to inform you about a notice from the market with one of our products.
Enclosed you will find the more detailed information about the product.

The National Institute for Drugs and Medical Devices (BfArM) has been informed.

According to our current assessment, there is no danger in using the product. We inform you as a precaution and ask for your cooperation.

on behalf

OSYPKA AG
Medizintechnik
Earl-H.-Wood-Str. 1
79618 Rheinfelden
Deutschland / Germany

[redacted]

Urgent Field Safety Notice (FSN)

VACSII 22x40 Cardiac valvuloplasty catheter

Review of the manufacturing documentation for a complaint report revealed that the balloon has a 1mm smaller diameter than specified. Based on this fact, it was decided that the complaint would be addressed as a Corrective and Preventive Action.

	1. Information on Affected Devices*
1.	2 Device Type(s)*
	Cardiac valvuloplasty catheter
1.	3 Commercial name(s)
	VACSII 22x40 Cardiac valvuloplasty catheter
1.	4 Unique Device Identifier(s) (UDI-DI)
	N/A
1.	5 Primary clinical purpose of device(s)*
	Valvuloplasty
1.	6 Device Model/Catalogue/part number(s)*
	YA0052
1.	7 Software version
	N/A
1.	8 Affected serial or lot number range
	P338820-06
1.	9 Associated devices
	N/A

	2 **Reason for Field Safety Notice (FSN)***
2.	2 Description of the product problem*
	The diameter of the balloon is smaller than internally specified
2.	3 Hazard giving rise to the FSCA/FSN*
	There is no hazard expected when the product is used according to the instructions for us (IFU),as the mounted balloon portion is in the range of the lower tolerance specifications of the productdescribed on the label. Only when the product is used off-label and inflated above the intendedrated burst pressure indicated on the label, there is a possibility that the product may bedamaged. Use without a pressure gauge would also be an off-label use.
2.	4 Probability of problem arising
	Rare.
2.	5 Predicted risk to patient/users

	No risk if the product is used according to the instructions for use. A prolongation of theintervention would occur only due to an exchange of the catheter to a one with bigger diameterduring the intervention, which is not expected.
2.	6 Further information to help characterise the problem
	N/A
2.	7 Background on Issue
	a complaint report revealed that the balloon has slightly smaller diameter than specified
2.	8 Other information relevant to FSCA/FSN
	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 Particular considerations for: VACSII 22x40 Cardiac valvuloplasty catheter Is follow-up of patients or review of patients' previous results recommended? No	
3.	3 Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	4 Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None CAPA is internally already generated to overcome this issue	
3	5 By when should the action be completed?	Already completed
3.	6 Is the FSN required to be communicated to the patient /lay user?	No
3	7 If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No	

	4. General Information*	
4.	2 FSN Type*	New
4.	3 For updated FSN, reference number and date of previous FSN	N/A
4.	4 For Updated FSN, key new information as follows:	
	N/A	
4.	5 Further advice or information already expected in follow-up FSN? *	No
4.	6 If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	7 Anticipated timescale for follow-up FSN	N/A
4.	8 Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	OSYPKA AG
	b. Address	Earl-H.-Wood-Str. 1 79618 Rheinfelden
	c. Website address	www.osypka.de
4.	9 The Competent (Regulatory) Authority of your country has been informed about this communication to customers. YES Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Germany	
4.	10 List of attachments/appendices:	No Attachment
4.	11 Name/Signature	[redacted]

	Transmission of this Field Safety Notice or Field Safety Corrective Action
	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 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.