Revision 1: November 22nd, 2022
FSN Ref: FSN_0002_Osypka_ FSCA _NCR_155_2022
FSCA Ref: FSCA_0002_NCR_155_2022

Date: 22.11.2022

Urgent Field Safety Notice (FSN)

Recall

regarding

VACSIII 22x40 Percutaneous Transluminal Valvuloplasty Catheter, YA 32240, LOT P351784-06
VACSIII 24x40 Percutaneous Transluminal Valvuloplasty Catheter, YA 32440, LOT P351384-05

Attn: to be completed by Sales

Dear Customer,

According to our records, you have received products from one or both of the above mentioned batches P351784-06 and P351384-05.

Based on customer feedback, we have determined that a mix-up occurred during the labelling process for these products. This means that the products labelled as VACSIII catheter size 22x40, item number YA32240 of batch P351784-06 actually contain VACSIII catheter size 24x40, item number YA 32440 of batch P351384 and vice versa.

Only products from the two mentioned batches are affected. Based on an internal check, we can exclude the possibility that other products are involved.

We therefore inform you as a precaution and ask for your cooperation in identifying and returning the products from the affected batches delivered to you. Please use the attached form for your response.

The following pages of this letter contain further information on the affected products, the possible risks for patients/users and the measures to be taken on your part.
The Federal Institute for Drugs and Medical Devices (BfArM) has been informed.

If you have any queries, please contact our Safety Officer/ PRRC Vigilance at the following contact details:

Dr. Nicola Osypka
…
E-mail: vigilance@osypka.de
Thank you in advance for your cooperation.
Yours sincerely,

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Ilse Karin Kastner
VP Sales

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

Urgent Field Safety Notice (FSN)

VACSIII 22x40 Percutaneous Transluminal Valvuloplasty Catheter, YA 32240, LOT P351784-06
VACSIII 24x40 Percutaneous Transluminal Valvuloplasty Catheter, YA 32440, LOT P351384-05

During a review of the manufacturing records for a claim, it was noted that balloon size 22 had a diameter 2mm larger than indicated on the label, and conversely, balloon size 24 had a diameter 2mm smaller. The laser print on the Y-piece corresponds to the actual balloon size in both cases.

	1. Information on Affected Devices*
1.	2 Device Type(s)*
	Percutaneous Transluminal Valvuloplasty Catheter
1.	3 Commercial name(s
	PTV Balloon Dilatation Catheter
1.	4 Unique Device Identifier(s) (UDI-DI)
	K.A.
1.	5 Primary clinical purpose of device(s)*
	Valvuloplasty
1.	6 Device Model/Catalogue/part number(s)*
	YA32240 und YA32440
1.	7 Software version
	K.A.
1.	8 Affected serial or lot number range
	P351784-06 und P351384-05
1.	9 Associated devices
	K.A.

	2 **Reason for Field Safety Notice (FSN)***
2.	2 Description of the product problem*
	The diameter of the balloon is larger or smaller than specified
2.	3 Hazard giving rise to the FSCA/FSN*
	A hazard is to be expected if the product is used according to the Instructions for Use (IFU), as the mounted balloon portion does not correspond to the indication on the package labels. If the discrepancy is not noticed during the preparation for surgery (comparison of label/Y-piece on the product), it may lead to the use of too large a catheter with possible fatal consequences
2.	4 Probability of problem arising

	Occasionally
2.	5 Predicted risk to patient/users
	Risk of fatal consequences when using a catheter size that is too large if the different designation on the label and Y-piece is not noticed.
2.	6 Further information to help characterise the problem
	K.A.
2.	7 Background on Issue
	In a complaint report, it was noted during the preparation for surgery that the size information for the balloon on the Y-piece and the packaging label were different.
2.	8 Other information relevant to FSCA/FSN
	K.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 Provide further details of the action(s) identified.The manufacturer's stock has been completely checked. No other similar products are affected. The error is limited to the two batches.	
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-Typ*	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/Unterschrift	**Dr. Nicola Osypka,** **PRRC**

	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 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.