Revision 1: 27.03.2024
FSN Ref: FSN_003_Osypka_ FSCA _NCR_036_2024
FSCA Ref: FSCA_003_NCR_036_2024

Datum: 27.03.2024

Urgent Field Safety Notice (FSN)

Recall

regarding

VACSIII 22x40 Percutaneous Transluminal Valvuloplasty Catheter, YA 32240, LOT P365941-07

Attn:

Dear Customer,

According to our records, you have received products from the mentioned batch **P365941-07**.

Due to customer feedback, we have discovered that there has been an error in the expiry date of these products.

We are therefore informing you as a precautionary measure and request your cooperation in identifying and returning the products delivered to you from the affected batch. Please use the attached form for your reply.

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:

Prof. Dr. Nicola Osypka
Earl-H.-Wood-Str. 1
79618 Rheinfelden
Germany
Tel: +49-(0)7623-7405-0
E-Mail: vigilance@osypka.de

Thank you in advance for your cooperation.

Yours sincerely,

Ilse Karin Kastner
VP Sales

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

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Urgent Field Safety Notice (FSN)

VACSIII 22x40 Percutaneous Transluminal Valvuloplasty Catheter, YA 32240, LOT P365941-07

After delivery of the above-mentioned product, one of our distributors made us aware of the described error.

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
1.	7 Software version
	K.A.
1.	8 Affected serial or lot number range
	P365941-07
1.	9 Associated devices
	K.A.

2. Reason for field safety corrective action (FSCA) or field safety corrective notice (FSN)*	
2.	2 Description of the product problem*
	wrong Expiry Date
2.	3 Hazard giving rise to the FSCA/FSN*
	There is no danger for users, patients and third parties if the product is used in accordance with the instructions for use (IFU).
2.	4 Probability of problem arising
	Occasionally
2.	5 Predicted risk to patient/users
	There is a risk that sterility cannot be maintained over the printed period because the expiry date was erroneously dated too far into the future.
2.	6 Further information to help characterise the problem
	K.A.

2. Reason for field safety corrective action (FSCA) or field safety corrective notice (FSN)*	
2.	7 Background on Issue
	One of our dealers has informed us that the expiry date is too far in the future.
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: n/a 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 Check inventory.	
3	5 By when should the action be completed?	done
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	**Prof. 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.

Rev 1: November 22nd, 2022

FSN Ref: FSN_0002_Osypka_ NCR_155_2022

FSCA Ref: FSCA_0002_NCR_155_2022

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Field Safety Notice (FSN)

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN_0002_Osypka_ NCR_155_2022
FSN Date*	22.11.2022
Product/ Device name*	VACS III 22x40 Cardiac valvuloplasty catheter VACSIII 24x40 Cardiac valvuloplasty catheter
Product Code(s)	YA32240 + YA32440
Lot/Serial Number (s)	P351784-06 + P351384-05

2. Distributor/Importer Details	
Company Name*	Pre-filled by manufacturer
Account Number	Pre-filled by manufacturer
Address*	Pre-filled by manufacturer
Shipping address if different to above	Pre-filled by manufacturer
Contact Name*	Pre-filled by manufacturer
Title or Function	Pre-filled by manufacturer
Telephone number*	Pre-filled by manufacturer
Email*	Pre-filled by manufacturer

3. customer action on behalf of the health organisation				
☐	I acknowledge receipt of the field safety notice and confirm that I have read and understood its contents.	Need to be filled by customer		
☐	I have carried out all the measures required by the FSN.	Need to be filled by customer		
☐	The information and necessary measures were brought to the attention of all relevant users and implemented.	Need to be filled by customer		
☐	I have returned the products concerned - indicate the number of products returned and the date of return.	Amount:	Lot/Serial nnumber: P351784-06	Date of return: (DD/MM/YY)
		Amount:	Lot/Serial nnumber: P351384-05	Date of return: (DD/MM/YYY)
		Comments:		
☐	I have destroyed the affected products - enter	Amount:	Lot/Serial nnumber: P351784-06	

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	the number of products destroyed and the date of completion.	Amount:	Lot/Serial nnumber: P351384-05
		Comments:	
☐	There are no affected products available for return/destruction.	Need to be filled by customer	
☐	Other action (define):	Need to be filled by customer	
☐	I do not have any affected products.	Need to be filled by customer	
☐	I have a question, please contact me (e.g. need to replace the product).	The customer enters his contact details, if different from those above, and a brief description of his concern Need to be filled by customer	
Name in block capitals		Please enter your name here	
Signature			
Date		Need to be filled by customer	

4. Return acknowledgement to Sender	**Mrs. Ilse Kastner**
Email	a.kaister@osypka.de, s.sommer@osypka.de
Distributor/Importer Helpline	+497623 7405209
Postal Address	**OSYPKA AG** Medizintechnik Earl-H.-Wood-Str. 1 79618 Rheinfelden Deutschland / Germany
Web Portal	www.osypka.de
Deadline for returning the Distributor/Importer reply form	December, 16th, 2022

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.