

Date: 22.11.2022

Urgent Field Safety Notice (FSN)

Recall

regarding

**VACSIll 22x40 Percutaneous Transluminal Valvuloplasty Catheter, YA 32240, LOT
P351784-06**

**VACSIll 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 VACSIll catheter size 22x40, item number YA32240 of batch P351784-06 actually contain VACSIll 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
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,

Revision 1: November 22nd, 2022

FSN Ref: FSN_0002_Osypka_FSCA_NCR_155_2022

FSCA Ref: FSCA_0002_NCR_155_2022



Ilse Karin Kastner
VP Sales

OSYPKA AG Medizintechnik

Earl-H.-Wood-Str. 1
79618 Rheinfeldern
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)* <u>Percutaneous Transluminal Valvuloplasty Catheter</u>
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* <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> 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 <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> 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
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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	
	<p>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)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>

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

	the number of products destroyed and the date of completion.	Amount:	Lot/Serial number: P351384-05
		Comments:	
<input type="checkbox"/>	There are no affected products available for return/destruction.	Need to be filled by customer	
<input type="checkbox"/>	Other action (define):	Need to be filled by customer	
<input type="checkbox"/>	I do not have any affected products.	Need to be filled by customer	
<input type="checkbox"/>	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, 16 th , 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.