

FSN: FSN_2026_002

Date: August 12, 2026

Urgent Field Safety Notice (FSN)

Product Advisory / Safety Advisory

concerning

VACS II/III Gen 2

Correction of selected product label information

Dear Customer,

According to our records, you have received products from the below-mentioned batches (Refer to Appendix 1 below). We have identified that certain data fields on the product labels contain information that does not fully align with the approved product records. The issue is limited to the labeling information and does not affect the quality, performance, safety, or intended use of the devices. The supplied VACS Gen 2 devices were manufactured in a fully compliant manner.

We are issuing this Product safety advisory in the form of Field Safety Notice (FSN) to inform you of the affected products and to provide the correct labeling information. As a precaution, please review the information provided in this notice and ensure that the corrected information is communicated to relevant personnel within your organization. We kindly ask you to complete and return the attached acknowledgment form.

The following pages of this letter contain further details on the affected products and the corrected labeling information. The competent authority "Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)" will be informed, as required.

If you have any questions, please contact our PRRC and CEO at the following contact:

Mr. Achim Kitschmann, Earl-H.-Wood-Str. 1 79618 Rheinfelden Germany, Tel: +49-(0)7623-7405-0, email: vigilance@osypka.de

We thank you in advance for your cooperation.

Best regards,

Signed by:

348577130049/BD

Ilse Kastner

VP Sales

1. Information on Affected Devices*

1	1. Device Type(s)*																																
	VACS II/III Gen 2 - Percutaneous Transluminal Valvuloplasty (PTV) Catheter																																
1	2. Commercial name(s)																																
	VACS® II/III Gen 2																																
1	3. Unique Device Identifier(s) (UDI-DI)																																
	Table 1: Affected REF numbers																																
	<table><tr><th>Affected REF Numbers (Device Model/Catalogue/part number(s))</th><th>Article Name</th><th>UDI-DI</th><th>Lot Number</th></tr><tr><td>YA232540</td><td>VACS III 25,0 x 40</td><td>04044508139646</td><td>P395735-02 P392014-02 P391846-02 P390877-02 P390534-02 P386790-02 P392103-02</td></tr><tr><td>YA232550</td><td>VACS III 25,0 x 50</td><td>04044508139660</td><td>P395496-02</td></tr><tr><td>YA232340</td><td>VACS III 23,0 x 40</td><td>04044508139547</td><td>P394918-02 P394813-02 P394435-02 P394166-02 P393941-02 P393940-02 P393623-02 P392521-02 P390532-02 P390531-02 P390530-02 P386780-02 P373518-02 P373517-02</td></tr><tr><td>YA232350</td><td>VACS III 23,0 x 50</td><td>04044508139561</td><td>P397062-02</td></tr><tr><td>YA230520</td><td>VACS III 5,0 x 20</td><td>04044508138922</td><td>P395492-02</td></tr><tr><td>YA230620</td><td>VACS III 6,0 x 20</td><td>04044508138946</td><td>P395493-02</td></tr><tr><td>YA230820</td><td>VACS III 8,0 x 20</td><td>04044508138984</td><td>P395732-02</td></tr></table>	Affected REF Numbers (Device Model/Catalogue/part number(s))	Article Name	UDI-DI	Lot Number	YA232540	VACS III 25,0 x 40	04044508139646	P395735-02 P392014-02 P391846-02 P390877-02 P390534-02 P386790-02 P392103-02	YA232550	VACS III 25,0 x 50	04044508139660	P395496-02	YA232340	VACS III 23,0 x 40	04044508139547	P394918-02 P394813-02 P394435-02 P394166-02 P393941-02 P393940-02 P393623-02 P392521-02 P390532-02 P390531-02 P390530-02 P386780-02 P373518-02 P373517-02	YA232350	VACS III 23,0 x 50	04044508139561	P397062-02	YA230520	VACS III 5,0 x 20	04044508138922	P395492-02	YA230620	VACS III 6,0 x 20	04044508138946	P395493-02	YA230820	VACS III 8,0 x 20	04044508138984	P395732-02
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1	4. Primary clinical purpose of device(s)*																																
	VACS II/III Gen2 is an over-the-wire catheter system for percutaneous transluminal valvuloplasty (PTV) used in the treatment of different kind of stenoses of cardiac vessels and/or structures and pre-dilatation in transcatheter heart-valve replacement procedures. They feature burst pressures suitable for resistant stenoses and have rapid inflation and deflation times to minimize procedure time and maximize reperfusion. Short, flexible distal tips with short balloon tapers aid maneuverability and trackability. They are available in a wide																																

	range of balloon diameters (4-30mm) and lengths (20-60mm).
1	5. Device Model/Catalogue/part number(s)*
	See table 1 above.
1	6. Software version
	n/a
1	7. Affected serial or lot number range
	Information is provided in table 1 above and Appendix 1 below.
1	8. Associated devices
	n/a

2. Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem* An internal review has identified that certain data fields contained on the labels of affected devices do not fully align with the approved product records. The issue is limited to labeling information only. Examples of affected fields may include: • Update to recommended introducer size • Update to Rated Burst Pressure (RBP)
2	2. Hazard giving rise to the FSCA* The labeling discrepancy may lead to user confusion regarding the correct use of the device; however, it does not affect the device's safety or performance.
2	3. Probability of problem arising The issue is present on all affected products listed in Appendix 1. However, the VACS Gen 2 devices contained within the affected packages are fully functional and remain safe and suitable for their intended clinical use. As the issue is limited to a labeling discrepancy and does not impact device safety or performance, the probability of a device-related problem arising is considered low.
2	4. Predicted risk to patient/users Issue 1: <u>Affected REF numbers:</u> YA232540, YA232550, YA232340, YA232350 <u>Advisory notice:</u> Healthcare professionals can use an introducer size (I) of 12F when using the device. The previously communicated recommended introducer size of 14F is no longer be considered the recommended size. <u>Predicted risk to patient/users:</u> The risk associated with this issue is considered low, and no impact on patient safety is expected. The introducer size is selected by the operating physician based on clinical judgment and patient-specific requirements. No patient injuries or adverse events related to this issue have been reported. Issue 2: <u>Affected REF numbers:</u> YA230520, YA230620, YA230820 <u>Advisory notice:</u> Healthcare professionals should consider an RBP of 10 bar when using the device. The previously communicated RBP value of 15 bar should no longer be

	considered the applicable device specification. <u>Predicted risk to patient/users:</u> The risk associated with this issue is considered low, and no impact on patient safety is expected. The actual Rated Burst Pressure (RBP) of the device is 10 bar, whereas the product labeling currently states an RBP of 15 bar. Internal testing has demonstrated device integrity at pressures exceeding the labeled RBP values. Although these data were not generated as part of formal design verification, they provide additional evidence that the device can tolerate pressures above the currently labeled range. Based on the available data and the absence of reported patient injuries, adverse events, or serious incidents, no adverse impact on patient safety is anticipated. Based on the manufacturer's assessment, no impact on device performance, quality, intended use, or patient safety has been identified.
2	5. Further information to help characterise the problem n/a
2	6. Background on Issue The discrepancy was identified during an internal review of labeling records. Investigation confirmed that the devices were manufactured, tested, and released in accordance with approved procedures. The issue is limited to specific label data fields.
2	7. Other information relevant to FSCA No adverse events or serious incidents associated with this issue have been reported.

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 - Review this Field Safety Notice (FSN) and share it with all relevant healthcare professionals. - Communicate this FSN to all relevant personnel within your organization. - Review the corrected product information provided in Appendix 1. - Update local reference materials, training materials, and procedural guidelines, as applicable, to reflect the updated information. - Consider the updated information for all future procedures involving the device. - No product return, product correction, product replacement, or product removal is required. - Maintain a copy of this notice with the applicable device records.

	Complete and return the attached acknowledgment form by 01 September 2026.	
3.	2. By when should the action be completed?	01 September 2026
3.	3. Particular considerations for: Choose an item. n/a 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 ☐ Software upgrade ☒ Other ☐ On-site device modification/inspection ☒ IFU or labelling change ☐ None - Correction of affected label information. - Notification of affected customers and distributors. - Implementation of preventive measures to avoid recurrence. - Update of internal labeling controls and verification procedures.	
3.	6. By when should the action be completed?	30 September 2026
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? No Not appended to this FSN	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	n/a
4.	3. For Updated FSN, key new information as follows:	
	n/a	

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:	n/a
4	6. Anticipated timescale for follow-up FSN	n/a
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Osypka GmbH
	b. Address	Earl-H.-Wood-Str. 1 79618 Rheinfelden, Germany
	c. Website address	www.osypka.de
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	Yes
4.	9. List of attachments/appendices:	Customer Acknowledgment Form
4.	10. Name/Signature	Achim Kitschmann PRRC and CEO

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.

Appendix 1: Affected Products and Corrected Label Information

Affected REF Numbers (Device Model/Catalogue/part number(s))	Article Name	UDI-DI	Lot Number	Advisory notice:	Predicted risk to patient/users
YA232540	VACS III 25,0 x 40	04044508139646	P395735-02 P392014-02 P391846-02 P390877-02 P390534-02 P386790-02 P392103-02	Healthcare professionals can use an introducer size (I) of 12F when using the device. The previously communicated recommended introducer size of 14F is no longer be considered the recommended size.	The risk associated with this issue is considered low, and no impact on patient safety is expected. The introducer size is selected by the operating physician based on clinical judgment and patient-specific requirements. No patient injuries or adverse events related to this issue have been reported.
YA232550	VACS III 25,0 x 50	04044508139660	P395496-02		
YA232340	VACS III 23,0 x 40	04044508139547	P394918-02 P394813-02 P394435-02 P394166-02 P393941-02 P393940-02 P393623-02 P392521-02 P390532-02 P390531-02 P390530-02 P386780-02 P373518-02		

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			P373517-02		
YA232350	VACS III 23,0 x 50	04044508139561	P397062-02		
YA230520	VACS III 5,0 x 20	04044508138922	P395492-02	Healthcare professionals should consider an RBP of 10 bar when using the device. The previously communicated RBP value of 15 bar should no longer be considered the applicable device specification.	The risk associated with this issue is considered low, and no impact on patient safety is expected. The actual Rated Burst Pressure (RBP) of the device is 10 bar, whereas the product labeling currently states an RBP of 15 bar. Internal testing has demonstrated device integrity at pressures exceeding the labeled RBP values. Although these data were not generated as part of formal design verification, they provide additional evidence that the device can tolerate pressures above the currently labeled range. Based on the available data and the absence of reported patient
YA230620	VACS III 6,0 x 20	04044508138946	P395493-02		

Affected REF Numbers (Device Model/Catalogue/part number(s))	Article Name	UDI-DI	Lot Number	Advisory notice:	Predicted risk to patient/users
YA230820	VACS III 8,0 x 20	04044508138984	P395732-02		injuries, adverse events, or serious incidents, no adverse impact on patient safety is anticipated.

Acknowledgment Form

Actions Required:

- Review the Field Safety Notice (FSN) “FSN-2026-002” and share it with all relevant healthcare professionals.
- Communicate the FSN to all relevant personnel within your organization.
- Review the corrected product information provided in Appendix 1.
- Update local reference materials, training materials, and procedural guidelines, as applicable, to reflect the updated information.
- Consider the updated information for all future procedures involving the device.
- No product return, product correction, product replacement, or product removal is required.
- Maintain a copy of this notice with the applicable device records.
- Complete and return the attached acknowledgment form by 01 September 2026.

☐ I acknowledge receipt and understanding of FSN-2026-002 regarding the correction of selected product label information and confirm that the information contained in this notice has been reviewed and communicated to all relevant personnel within our organisation.

Organization:

Name:

Title:

Signature:

Date: