Date: October 2020
FSN Ref: FSN20-64C16

Urgent Field Safety Notice

Regarding the voluntary recall action of two batches of RESTORE DEB Paclitaxel Releasing PTCA Balloon Catheter

For Attention of*: Chief Executive /Risk Management/ Purchasing

Contact details of local representative (name, e-mail, telephone, address etc.)*
CARDIONOVUM GmbH, Am Bonner Bogen 2, 53227 Bonn, Germany; E-Mail: Jolanthe.Mendt@cardionovum.com; Phone: +492289090590 For any further information or support concerning the information within this FSN, please contact your local CARDIONOVUM Medical Sales Agent.

CARDIONOVUM

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	Information on Affected Devices*
1	1. Device Type(s)*
	RESTORE DEB Paclitaxel Releasing PTCA Balloon Catheter is a double Lumen coronary balloon dilatation catheter for rapid exchange, with a balloon that can be enlarged and two radiopaque markers (proximal and distal), to facilitate the balloon positioning under X-ray fluoroscopy. The RESTORE DEB PTCA balloon is coated with 3.0 µg Paclitaxel per mm². The dilatation balloon is designed to inflate to a known diameter and length at recommended inflation pressures (refer to Compliance Chart). The proximal end of the RESTORE DEB PTCA catheter has a single female Luer-Lock port to inflate/deflate the balloon. The RESTORE DEB PTCA is a Rapid Exchange catheter with a working length of 140 cm and a guide wire lumen of 25 cm length. The RESTORE DEB PTCA catheter is compatible with guide wires of 0.014" (0.36 mm) diameter and guiding catheters with 5F.
1	2. Commercial name: RESTORE DEB Paclitaxel Releasing PTCA Balloon Catheter
1	3. Primary clinical purpose of device(s)*
	The RESTORE DEB catheter is used for the treatment of coronary artery disease (CAD). The intended use of the RESTORE DEB catheter is to improve the luminal diameter of coronary arteries. The RESTORE DEB catheter is indicated for the dilatation of coronary in-stent restenosis (ISR) and small vessel de novo lesions (less than 3.0 mm).
1	4. Device Model/Catalogue/part number(s)* REF no. RX3.50 -25mm
	Add as Appendix if necessary.
1	5. Affected serial or lot number range Lot numbers: C50/3/20 C18/5/20

	Reason for Field Safety Corrective Action (FSCA)*
2	1. Description of the product problem*
	According to one customer complaint from China, the doctor has found that the marking of the product size placed on the HUB was incorrectly marked. As correctly printed on the label of the primary and secondary packages, the size 3.50– 25 mm should also be printed on the HUB. In this case the HUB was marked with the wrong number 2.50 – 25 mm. It is possible that in the two batches of balloon catheters there are products, which may have incorrect marking on the hub.
2	2. Hazard giving rise to the FSCA*
	Potential confusion of the doctor.
2	3. Probability of problem arising
	If the doctor hadn't noticed the wrong marking on the hub, the patient would not be in danger because the product itself had the correct size. There is no risk for the patient as the correct size has been marked on the label on the primary and secondary package. Usually the doctor follows the label to choose the correct size. The incorrect marking on the hub could generate confusion in the clinician. In case of above mentioned customer complaint the doctor decided to not use the product.

2	4. Predicted risk to patient/users
	No risk for patients.
2	5. Background on Issue
	The hub is the part of the basic balloon catheter attached to the proximal end of the device. The size on the HUB is pre-marked and added to every finished balloon catheter device, but the size on the HUB does not determinate the size of the device. However, the proper size of the balloon catheter should appear also on the HUB. The HUB from the complaint was marked incorrectly. However, the doctor chooses the product size according to the label on the outer box and sterile package. All these other labels were correct, as well as the sizing of the balloon of the device itself.
2	6. Other information relevant to FSCA
	Cardionovum has sold more than 42,000 RESTOREs since the product was approved in 2011. This is the first time that CARDIONOVUM has received this kind of complaint.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the distributor / 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 Please complete the enclosed Distributor Reply Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue with the relevant Return Authorization number. Please include contact details on the Customer Response form. Returned Product should be addressed to: CARDIONOVUM GmbH Am Bonner Bogen 2 D- 53227 Bonn In case you have already provided the products to the end user, we add the Customer Reply Form to be sent to the end customer.	
3.	2. Is customer Reply Required? * (Till 30.11.2020)	Yes
3.	**3. 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.	
3	4. By when should the action be completed?	Specify where critical to patient/end user safety
3.	5. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	Choose an item.
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**CARDIONOVUM GmbH**
	b. Address	**Am Bonner Bogen 2**
	c. Website address	**www.cardionovum.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	6. Name/Signature	**Jolanthe Mendt**

	Transmission of this Field Safety Notice
	This notice needs to be passed on to 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.