FSN Ref: REC-000384 FSCA Ref: REC-000384

Date: YYYY:MM:DD

Field Safety Notice
Perceval Plus Sutureless Aortic Heart Valve

For Attention of: Vigilance organisms and Users of the Perceval Plus Suturless Aortic Heart Valve involved in the stock management and implantation of the models listed in the enclosed Attachment A.

Contact details of local representative (name, e-mail, telephone, address etc.)
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

Reason: Possible presence of particulate in the finished product.

Dear Valued Customer,

You are receiving this letter because, according to our records, the Perceval Plus Sutureless Aortic Heart Valves listed in Attachment A (Return Form) have been shipped to your facility. These devices are part of a Field Safety Corrective Action issued by Corcym S.r.l..The remainder of this notice details what is prompting this action, what will need to be done with the affected products and the Corcym contacts that can provide assistance.

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Perceval Plus Suturless Aortic Heart Valve
Risk addressed by FSN

1. Information on Affected Devices	
1.	1. Device Type(s)
	PERCEVAL PLUS is a bioprosthetic valve with the unique characteristic of allowing sutureless positioning and anchoring at the implant site. The choice of materials and configuration ensures the device's biocompatibility and haemocompatibility. PERCEVAL PLUS prosthesis consists of a tissue component made from bovine pericardium stabilized in buffered glutaraldehyde solution and a self-expandable Nitinol stent, which has the dual role of supporting the valve and fixing it in place. The bovine pericardium is subjected to a phospholipid's reduction treatment. The prosthesis is sterilized with a glutaraldehyde-based solution and then treated for the neutralization of free aldehyde residues. PERCEVAL PLUS tissue heart valve is supplied unmounted. Prior to implantation the prosthesis diameter is reduced to a suitable size for loading it on the holder. The valve is then positioned and released in the aortic root, where the stent design and its ability to apply a radial force to the annulus allow stable anchoring of the device. The prosthesis is then finally packaged using an aseptic transfer process and stored in a buffered solution without aldehydes.
1.	2. Commercial name(s)
	Perceval Plus Suturless Aortic Heart Valve
1.	3. Unique Device Identifier(s) (UDI-DI)
	08022057015365 PVF-S 08022057015372 PVF-M 08022057015389 PVF-L 08022057015396 PVF-XL
1.	4. Primary clinical purpose of device(s)
	PERCEVAL PLUS prosthesis is intended to replace a damaged native aortic heart valve or a malfunctioning aortic prosthesis via open heart surgery.
1.	5. Device Model/Catalogue/part number(s)
	PVF-S, PVF-M, PVF-L, PVF-XL
1.	6. Affected serial or lot number range
	The affected serial numbers are listed in Attachment A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	Corcym discovered that some polymeric particles, originated from one of the equipments used for the terminal sterilization process, may be present in the finished products listed Attachment A. These particles were demonstrated to be fully biocompatible and in vast majority <100 microns in size
2.	2. Hazard giving rise to the FSCA
	If particles, that may happen to be on the valve, enter the body, there is a risk that they migrate within the immediate postoperative phase. Based on particle size, and the different mitigating activities that are normally adopted prior and during the implant procedure, such as the placement of the valve in a bowl of saline prior to the implant, Corcym has assessed that the risk of injury to patients implanted with an affected device is low. However, Corcym has conservatively decided to recall all unused devices.

3. Type of Action to mitigate the risk			
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device Corcym is coordinating the removal of all potentially affected Perceval Plus valves in your inventory. Please ensure timely execution of the following actions: 1. using the list provided in Attachment A, check your inventory for potentially affected devices supplied at your facility and still on the shelves. 2. Segregate and put in quarantine the affected valves identified as per point 1. 3. Complete and return Attachment A (Return Form) by e-mail to FSCA@corcym.com to initiate the return process of the affected Perceval Plus valves. Your Corcym Representative will contact you to coordinate the return of the affected device(s) to Corcym S.r.l.		
3.	2. By when should the action be completed?	Activities listed in points 1, 2, 3 above shall be completed by January 8th, 2024.	
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 Your Corcym Representative will contact you to coordinate the return of the affected device(s) to Corcym S.r.l.		
3.	5. By when should the action be completed?	March 1st, 2024	
3.	6. Is the FSN required to be communicated to the patient /lay user?	No	

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4. General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Corcym S.r.l.
	b. Address	Strada Crescentino, 13040 Saluggia (VC) - Italy
	c. Website address	www.corcym.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Attachment A (Return Form)
4.	6. Name/Signature	Laura Mannino Customer Quality Manager
		

	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.