FSN Ref: REC-000703 FSCA Ref: REC-000703

Date: 2025/01/17

Field Safety Notice

CARBOMEDICS PROSTHETIC HEART VALVES

CARBOMEDICS CARBO-SEAL® AND CARBO-SEAL® VALSALVA ASCENDING AORTIC PROSTHESES

For Attention of: Vigilance organisms and Users of the Carbomedics Prosthetic Heart Valves and Carbomedics Carbo-Seal® and Carbo-Seal® Valsalva Ascending Aortic Prostheses 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 leaflet thickness non-compliant to specifications.

Dear Valued Customer,

You are receiving this letter because, according to our records, the Carbomedics devices listed in Attachment A (Return Form) of this Field Safety Notice 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.

FSN Ref: REC-000703 FSCA Ref: REC-000703

Field Safety Notice (FSN)

CARBOMEDICS PROSTHETIC HEART VALVES

CARBOMEDICS CARBO-SEAL® AND CARBO-SEAL® VALSALVA ASCENDING AORTIC PROSTHESES

Risk addressed by FSN

1. Information on Affected Devices	
1.	1. Device Type(s)
	The Carbomedics Prosthetic Heart Valve (CPHV) is a low profile bileaflet prosthesis. The CPHV sub-assembly consists of an orifice housing and two identical mobile leaflets, which articulate almost entirely within the orifice. The leaflets and orifice utilize Pyrolitic carbon, a material used extensively in mechanical heart valves. The valve leaflets are constructed of Pyrolitic carbon, coated over a tungsten impregnated graphite substrate to enhance radiopacity. The valve orifice consists entirely of solid Pyrolitic carbon reinforced by a titanium stiffening ring which minimizes the potential for orifice deformation. The titanium ring, combined with the radiopaque leaflets, allows for non-invasive assessment of valve leaflet motion using fluoroscopy or similar methodologies. The sub-assembly orifice-leaflets can be mounted both on mechanical valves or on Carboseal/Carboseal Valsalva ascending aortic prostheses.
1.	2. Commercial name(s)
	Carbomedics Prosthetic Heart Valves - Carbomedics Carbo-Seal® and Carbo-Seal® Valsalva Ascending Aortic Prostheses
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)
	The Carbomedics Prosthetic Heart Valve is intended for use as a replacement valve in patients with diseased, damaged, or malfunctioning aortic or mitral heart valve.This device may also be used to replace a previously implanted aortic or mitral prosthetic heart valve. The Carbomedics Ascending Aortic Prostheses are intended for use in open heart surgery for simultaneous replacement of the ascending aorta and the aortic valve in cases of aneurysm, dissection, or other disease conditions of the aorta combined with disease or degeneration of the aortic valve.
1.	5. Device Model/Catalogue/part number(s)
	The affected models are listed in Attachment A
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 detected that the products listed in Attachment A might present leaflets with a thickness of the Pyrolitic carbon coating below specifications.
2.	2. Hazard giving rise to the FSCA
	Should a device with a leaflet possessing a too thin Pyrolytic carbon coating be implanted, the leaflet may experience accelerated wear over time. Such an occurrence could result in a potential failure leading to steno-insufficiency, acute or progressive cardiac failure, and serious patient injury. Corcym is undertaking extensive testing to ascertain the likelihood of the Pyrolytic carbon coating thickness being below specifications in the affected components. Although these tests are ongoing and further confirmation is required, preliminary results suggest that this probability is very low. Additionally, testing and simulations are being conducted to evaluate the impact of out of specification leaflet thickness on valve durability. The results of these assessments are anticipated to be available by mid-February.

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 prostheses 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 devices. Your Corcym Representative will contact you to coordinate the return of the affected device(s) to Corcym S.r.l. Regarding patients already implanted with the affected valves, until the results of further testing and simulations will be available, the following aspects should be taken into consideration: • based on the analysis performed so far, the probability of the Pyrolitic carbon coating being below spec is expected to be very low; • in case of a leaflet with a thin Pyrolitic carbon coating (i.e. below product specification), the possible failure mode is related to wear and, as such, is expected to occur over time.	
3.	2. By when should the action be completed?	Activities listed at points 1-2 shall be completed as soon as possible, no later than January 24, 2025. Activity listed at point 3 shall be completed by January 31, 2025
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 31st, 2025	
3.	6. 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?	Yes
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	
	b. Address	
	c. Website address	
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	

	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.