URGENT FIELD SAFETY NOTICE

Potential failure of the AESON Total Artificial Heart

Commercial name of the affected product: AESON Total Artificial Heart

FSCA reference: G000062421/02

Date: December 21, 2021

To the attention of: Physicians, Healthcare professionals, Medical centers

Type of action: Instructions provided by manufacturer regarding the follow-up of patients

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Dear Customer,

Carmat has identified that one component of its Prosthesis generating blood flow might fail through the investigation of two serious adverse events that occurred between mid-November and beginning of December 2021:

* One patient died from acute pulmonary oedema soon after the Prosthesis raised an alarm suggesting a malfunction of the auxiliary pump

* The Prothesis of another patient had to be replaced in emergency after it had shown similar symptoms of malfunction

The investigation has determined that both failure modes are unrelated and independent from each other.

Description of the issue

While the right ventricle of the Prosthesis would keep operating and generating a nominal blood flow, the efficacy of the left ventricle would decrease up to a point where the unbalanced blood flow generated by the ventricles would cause a massive congestion of the pulmonary circulation.

Possible consequences of the issue

If the emergency procedure is not initiated soon after an “Emergency heart failure” alarm[1] is raised, the patient would die from the pulmonary oedema.

Actions taken by Carmat to correct the problem

While the investigation is being conducted, Carmat has decided to suspend the implantation of its device for both clinical and commercial purposes.

Carmat will provide a reliable estimate of the probability of failure once the root causes have been determined.

Carmat recommends the centers to place their currently implanted patients on the high priority transplant lists. Nevertheless, in case of alarms suggesting a device failure, the Prosthesis should be replaced following the Emergency Procedure[2]. This procedure allows for the defective Prosthesis to be replaced with a backup

[1] High level alarms: D007, D008, D011, D012, D013, D050, D052
Medium level alarms: D009, D010, D014, D061, D132, D133

[2] The Emergency Procedure is described in section 12.1 of the Clinician manual.

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Prosthesis. This needs to be done within a short timeframe and requires a backup Prosthesis to be available at the hospital. Because the time to stabilize the blood circulation is critical, the medical team needs to determine on a case-by-case base if local circumstances allow for discharged patients to remain at home.

Carmat will provide a Backup system to your center if none is currently available on site.

Carmat does not recommend performing prophylactic device replacements.

Transmission of this Field Safety Notice:

Please complete and return the Customer Reply Form as soon as possible to acknowledge that you have read and understood this Field Safety Notice.

This notice needs to be passed on all of those who need to be made aware within your organization.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

CARMAT SA contact person:

- **Name:** Laura Ouaki
- **Function:** Customer Quality Manager
- **Organization:** CARMAT SA
- **Address:** Immeuble l'Etendard
  36, avenue de l'Europe
  78140 Vélizy-Villacoublay
  FRANCE
- **Contact details:** carmat.fsca@carmatsas.com

Carmat has communicated this notice to the Competent Authority of your country.

We apologize for the inconvenience that the issue described here above is causing to your organization and to the patient.

Signature:

Customer Reply Form

FSN Reference: G000062421/02 – Potential failure of the AESON Total Artificial Heart

FSN date: December 21, 2021

Device: AESON TAH

Please complete and return this form to the Carmat contact person.

Customer Details	
Organization name	
Organization address	
Department/Unit	
Contact name	
Telephone number	
Email	

Customer Actions undertaken	
☐ I confirm receipt of the Field Safety Notice. The information and requirements have been brought to the attention of all relevant users.	
☐ I have a query, please contact me.	
Printed Name	
Title	
Date (DD/MM/YYYY)	
Signature	