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4 June 2021

Urgent Field Safety Notice –

Type of Action: Advisory

The SynCardia TAH-t System

The SynCardia temporary Total Artificial Heart (TAH-t) System with the SynCardia Freedom Driver is indicated for use as a bridge to transplantation in cardiac transplant eligible candidates who are implanted with the TAH-t and are clinically stable.

SynCardia is notifying clinicians at our European implant centers of a potential risk associated with the use of the Freedom Driver for patients who are not clinically stable. Patients who are not clinically stable should be supported by the Companion 2 (C2) Driver.

The TAH-t System

The SynCardia TAH-t System is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from biventricular failure. The SynCardia temporary Total Artificial Heart (TAH-t) System is a pulsatile biventricular device that replaces a patient's native ventricles and valves and pumps blood to both the pulmonary and systemic circulation. The system consists of the implantable TAH-t and an external pneumatic driver connected by drivelines.

The C2 Driver provides pneumatic power to operate the SynCardia TAH-t. The C2 operates and monitors the TAH-t throughout its implantation, surgical recovery phase, and the ambulatory and ongoing phases of patient support. The C2 Driver System includes a Driver, a Hospital Cart and a Caddy. The C2 2 Driver System, used with the 50cc TAH-t or the 70cc TAH-t, is intended for use inside the hospital and on the hospital grounds.



The SynCardia Freedom Driver System, used with the 50cc TAH-t or the 70cc TAH-t, is intended for in-hospital and out-of-hospital use. The TAH-t System with the SynCardia Freedom Driver is indicated for use as a bridge to transplantation in cardiac transplant-eligible candidates who are implanted with the TAH-t and are clinically stable.

Throughout the bridge to transplant period, a patient discharged from hospital, supported by the Freedom Driver, who would present a clinical situation synonym of clinical instability, should be switched back to the C2 Driver and have further evaluation by the supporting Heart Failure team in the hospital which has performed the TAH-t implant.

Description of the problem

In all cases, a clinically unstable patient should be switched back to the C2 driver and monitored appropriately, as per our Instructions For Use (IFU).

The Freedom Driver is indicated only for patients that are clinically stable.

The Freedom Driver fill volume measurement and readings are accurate within +/- 20% in clinically stable and euvolemic patient conditions. If a hypervolemic and/or hypertensive condition occurs, a situation independent of the way the Freedom driver operates, the calculated fill volume readings may have the potential to be significantly reduced against the real fill volume which may result in a fault alarm. The inherent risk of this occurrence is that medical personnel may incorrectly assess the physical condition of the patient solely on the display readings and provide treatment such as administration of intravenous fluids to correct the presumed low cardiac output/hypovolemic state which may further increase the hypervolemic and/or hypertensive condition.

Potential clinical effects

If patients become unstable, a reasonable probability exists that the Freedom Driver fill volume inaccuracies may result in serious adverse health consequences that may be transient in nature and/or require medical intervention. If the left filling volume or the systemic vascular resistance increase to a level that cannot be overcome by the Freedom Driver, ejection of blood from the left side of the heart may be reduced and cause back-up of blood in the right side of the heart resulting in flash pulmonary edema and symptoms of right-sided heart failure. If the clinical condition is not identified and corrected in a timely manner, it could progress to circulatory collapse and death. There have been no reported permanent injuries or deaths associated with these events.



Recommended actions

It is recommended that patients transfer to the Companion 2 Driver for further assessment to guide medical therapy in the following clinical states as they may result in Freedom Driver miscalculations of cardiac output readings.

- If the patient becomes unstable.
- If a hypervolemic or hypertensive state develops.
 - A clinical examination of the patient should always be conducted when looking for clinical signs of hypervolemia versus hypovolemia, which may prevent providing treatment such as administration of intravenous fluids to correct the presumed low cardiac output/hypovolemic state which may further increase the hypervolemic and/or hypertensive condition.
- If continuous or persistent intermittent or fault alarms occur.

In clinically stable euvoletic patient conditions, the Freedom Driver fill volumes and cardiac output readings may be used to assess fluid status trends.

Actions to be taken by SynCardia

SynCardia will update the Freedom Driver IFUs with information on recommended actions to take and associated risks.

SynCardia will train clinicians to the updated labeling.

Contact

If you have any questions or comments regarding this notice, please contact your SynCardia distributor, Eric Lambert, Sr Director International Sales & Marketing, at elambert@syncardia.com or Regulatory Affairs at regaffairs@syncardia.com.

The applicable Competent Authorities will be notified of this action.



Customer Acknowledgment Form

Please complete this Customer Acknowledgment Form and return it via email **within five business days of receipt of this letter to:**

SynCardia Systems, LLC
Attn.: Regulatory Affairs
Email Address: regaffairs@syncardia.com

Please check the box to acknowledge receipt of the notification.

I have read and understand the notification

Printed name of person	Facility/Business Name
Signature	Date:
Address and City	
SynCardia Distributor or Sales Representative	
Telephone:	
Date the notification was received:	