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28 May 2021

Urgent Field Safety Notice

Type of Action: Advisory

The SynCardia TAH-t System

This is to notify clinicians at our European implant centers that there have been reported customer complaints for the CPC connectors that fasten the TAH-t cannulae to the external Driver drivelines. The spring inside the female CPC connector housing may become displaced inside or dislodged from the housing when the wire (zip) tie is inserted or removed incorrectly from the CPC connector during or after a Driver exchange/switch.

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.

Description of the problem

The spring inside the female CPC connector housing may become displaced inside or dislodged from the housing when the wire (zip) tie is inserted or removed incorrectly from the CPC connector during or after a Driver exchange/switch, preventing disconnection of the cannula and exchanging of Drivers. **See Figures 1-3**

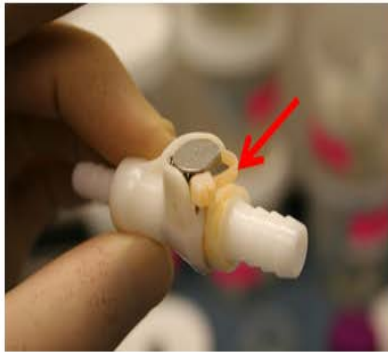


Figure 1
Wire Tie at CPC Junction



Figure 2
Displaced CPC Spring

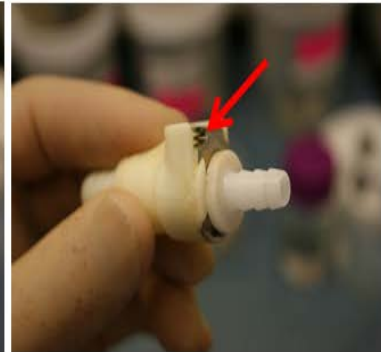


Figure 3
Correctly Seated CPC Spring

Potential clinical effects

Risks associated with the CPC connector spring displacement or dislodgement are isolated to patients implanted with the TAH-t who are supported with the Companion 2 Driver and Freedom Driver in and out of the hospital setting.

The probability exists that the CPC spring displacement related to the wire ties may result in serious adverse health consequences that may be transient in nature and/or require medical intervention. The probability is remote ($0.001\% < F \leq 0.1\%$) based on the estimated rate of injury occurrence associated with CPC connector malfunctions reported to SynCardia. The primary risk of injury could be caused by a more difficult disconnection of the cannula and drivelines which may impact the ability to complete a driver exchange in a timely manner that could result in a loss of power to the TAH-t.

Recommended actions

- **Patients**
 - Must return to clinical site for CPC connector repair and/or exchange
- **Clinicians**
 - In the event of a displaced spring on the left side cannula CPC connector, it is recommended that the CPC connector be replaced.
 - Replacement is accomplished by attaching a new CPC connector onto a pumping TAH-t Driver system driveline and then cut the securing wire ties on the patient cannula hose barb.
 - Remove the hose barb from the patient cannula and immediately insert the hose barb of the new CPC connector that is pumping on the new driver. Secure the cannula with new wire ties.
 - Repeat this on the other ventricle side if needed.
 - If there is no need to change the right, male, CPC connector, just attach the new Driver Right Driveline to the blue, right, cannula fitting.



Actions taken by SynCardia

A training video was created that provides patients and caregivers guidance on securing the CPC connectors with wire ties: Clinical-529, *Training Video: Securing CPC Connector with Wire Tie* and will be available on SynCardia's website (www.syncardia.com) under the Patient or Clinical Resources on 02 Jun 2021.

Actions to be taken by SynCardia

SynCardia will update the Freedom Driver System and Companion 2 Driver System IFUs with instructions to enable the user to correctly insert the wire (zip) tie, identify displaced or dislodged springs within the CPC connector housing and instructions for clinicians to repair and/or exchange the CPC connector. The IFUs will be updated with risks associated with this failure mode.

SynCardia currently has a design change for a CPC cover that mitigates this problem. This design change is under review by the competent authority.

Contact

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

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The applicable Competent Authorities will be notified of this action.

Customer Acknowledgment Form – CPC Connector

Please complete this Customer Acknowledgment Form and return it via Email to SynCardia Systems, LLC. **within five business days of receipt of this letter.**

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:	