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06 May 2021

Urgent Field Safety Notice – FSN20213004-02

Type of Action: Advisory

SynCardia Companion 2 (C2) Driver System (Catalog # 397002-001)

This is to notify clinicians at our European implant centers of a C2 mechanical valve timing issue that may lead to a decrease in cardiac output, or a pressure imbalance between the left and right ventricles.

- Implemented Corrective Action: A two-year service interval was reduced to 90 days of use. It is important to note that since the shorter interval was fully implemented in October 2019, we have not received any reported valve timing issues.

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 TAH-t System consists of the implantable TAH-t, an external pneumatic driver, drivelines, and other accessories.

The C2 Driver provides pneumatic power to operate the SynCardia TAH-t in the form of synchronized pulses of air that flex the heart's diaphragms to circulate blood in a patient's body. 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.

Description of the problem

If an asynchronization of valve actuation between the C2's two pilot valves occurs, it will result in an activation timing difference between the valves. The timing issue

can be observed on the C2 monitor screen as a separation between the ventricles' systolic and diastolic waveforms at the beginning of the diastolic fill cycle. See **Figure 1** for an illustration of separated air flow waveforms at the beginning of a diastolic fill cycle.

Potential clinical effects and recommended actions

A C2 valve timing issue may also cause the following alarms:

1. A "Low CO" alarm, if the calculated cardiac output drops below 3.5 liters per minute on either the left or right ventricle; or
2. A right/left Imbalance alarm, if the calculated cardiac outputs are not within approximately 50% of each other.

A clinician monitoring a patient on a C2 Driver should switch the patient to a backup driver immediately after observing:

1. A divergence in pressure waveforms, as illustrated in **Figure 1**
2. An unexpected drop in cardiac output for one of the ventricles, or
3. A right/left pressure imbalance alarm.



Figure 1 – A waveform divergence in the top-right graph

Actions taken by SynCardia

SynCardia has identified the root causes of the issue to be particulate contamination from the incoming air supply, or from the valve not completely



closing due to residual electrical drop-off current applied to the valves when they are not activated.

We have implemented a shorter change-out maintenance interval, from two years to 90 days of use. It is important to note that since the shorter interval was fully implemented, we have not received any reports of the issue since October 2019.

In addition, proposed changes to suppliers, valves, and the electrical timing current to ensure the valves close fully and are fully activated are currently under regulatory review by European Union regulatory authorities.

Actions to be taken by SynCardia

SynCardia will update the Companion 2 Driver Operator Manual with information to enable the user to specifically identify the waveform timing discrepancy and the risks associated with this failure mode.

SynCardia will provide additional training to users to specifically identify the waveform timing discrepancy and the risks associated with this failure mode.

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.

The applicable Competent Authorities will be notified of this action.



Customer Acknowledgment Form - FSN20213004-02

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:	