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20 May 2021

Field Safety Notice – FSN20213004-01_Rev 002

Type of Action: Advisory

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

Summary of August 2018 U.S. Food and Drug Administration (FDA) Letter to Healthcare Providers

This is to notify transplant surgeons and cardiologists at our European implant centers of the 2018 FDA letter to healthcare providers regarding the final results of our post-approval study that compared clinical results between patients initially supported by our legacy driver, the Circulatory Support System (CSS) Console, and those initially supported by our current support system, the C2 Driver System.

The current SynCardia 50cc and 70cc TAH-t Instructions for Use with the Companion 2 Driver System do not have the results of this study.

It is important to note that the CSS Console was taken out of service in Europe by 2014 and globally by April 2018, prior to the issuance of the 2018 FDA letter.

The TAH-t System and C2 Driver

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

The C2 Driver provides pneumatic power to operate the SynCardia TAH-t in the form of synchronized pulses of air that flex the TAH-t 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.

Study Mortality results

overall post-implant survival was assessed at three and six months. Overall survival through three months was 65.5% of the 200 patients in the C2 Driver Cohort (C2 cohort) and 77.5% of the 89 patients in the CSS Console cohort (CSS cohort). At six months, the C2 cohort had a 60% survival rate compared to 74.2% patient survival on the CSS cohort.

Patients who received pre-implant circulatory rescue

For patients who received pre-implant intervention such as extracorporeal membrane oxygenation (ECMO) or an intra-aortic balloon pump, survival rates at three months were 58.4% for patients in the C2 cohort and 79.2% for in the CSS cohort. Six-month survival was 55.8% for the C2 cohort and 72.9% for the CSS cohort.

Patients who did not receive pre-implant circulatory rescue

For those patients who did not receive pre-implant circulatory rescue, the three-month survival rate was 69.9% for the C2 cohort and 75.6% for the CSS cohort. Six-month survival was 62.6% for patients on the C2 cohort and 75.6% for those on the CSS cohort.

Stroke

Data were also collected for incidences of stroke in patients while supported by a SynCardia circulatory support system and showed that the stroke rate was higher for patients in the C2 cohort compared to those on the CSS cohort, irrespective of pre-implant interventions. Three-month stroke rates were 26.5% for patients in the C2 cohort and 7.9% for those in the CSS cohort. At six months, the stroke rate for the C2 cohort increased slightly to 27% while the stroke rate for CSS cohort remained at 7.9%.

Data limitations

As the FDA noted in their letter, *“although the differences in mortality and stroke outcomes in this study are notable, we do not know the root cause for these observed differences, and the results are not adjusted for potential confounders. Cohort designation was ‘as-treated,’ based upon a subject’s initial driver system at time of TAH-t implantation; any effects due to driver system exchanges within 6 months are therefore not captured by these results.”*



There were data limitations that must be considered when evaluating the results of the study. Driver switch out between the CSS and C2 drivers after date of implant within the six-month period are not reflected in the data, so any effects due to driver system exchanges during the study period could not be assessed.

Recommendations to healthcare providers

In its letter, FDA recommended that healthcare providers consider the mortality and stroke results of the study when making treatment decisions, and discuss risks and benefits of the C2 Driver System with their patients.

More information

The full text of the 2018 FDA letter can be found at [SynCardia Systems - TAH-t Companion 2 Driver System \(C2\) and Risk of Mortality and Stroke - Letter to Health Care Providers | FDA](#) and the final PAS data page is located at [Post-Approval Studies \(PAS\) Database \(fda.gov\)](#).

In an article published in 2018 in the Journal of Heart and Lung Transplant (Interagency registry for mechanically assisted circulatory support) report on the total artificial heart, Dr Francisco Arabia analyzed the INTERMACS® data of 450 patients who received a SynCardia TAH between June 2006 and April 2017. Competing outcome analysis showed 71% of patients in high-volume center were alive on the device or had undergone transplantation at 12 months after TAH implantation vs 57 in low-volume centers (p = 0,003). Dr Arabia's conclusion states: **Experienced centers have better outcomes, likely related to patient selection, timing of implantation, patient care, and device management.**

- Arabía FA, Cantor RS, Koehl DA, et al. [Interagency registry for mechanically assisted circulatory support report on the total artificial heart](#). The Journal of Heart and Lung Transplantation. 2018;37(11):1304-1312. doi:10.1016/j.healun.2018.04.004

Action by the Company:

SynCardia will update the current IFU with the results from the SynCardia Companion 2 Driver System With Intermacs®-Based Data Collection.

Contact

We ask that our implant centers continue to contact SynCardia via their distributor to report any adverse events or suspected adverse events related to the TAH-t System products as soon after the event as possible. Devices associated with, or suspected to be associated with, any adverse events should be returned to us for evaluation to help better understand the issue.

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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.

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Customer Acknowledgment Form - FSN20213004-01_Rev 002

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

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Signature	Date:
Address and City	
SynCardia Distributor or Sales Representative	
Telephone:	
Date the notification was received:	