SynCardia Systems, LLC
1992 E. Silverlake Rd.
Tucson, Arizona 85713
Telephone: 520.545[redacted]
Facsimile: 520.903.1782

<<Distributer Name>>
<<User_Name>>
<<Department>>
<<Customer_Address>>
<<Postal Code>> <<City>>
<<Country_name>>

21 December 2021

Urgent Field Safety Notice – RA-1720 Rev 001

Type of Action: Advisory

SynCardia TAH-t System

This is to notify our economic operators and our European Union (EU) implant centers of Supply Chain issues we have encountered that will impact future implants and opening of new sites. Imminent Supply Chain disruptions linked to Regulatory and logistical factors, impacted by COVID-19 and legislative obligations.

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

Imminent Supply Chain disruptions linked to Regulatory and logistical factors, impacted by COVID-19 and legislative obligations.

SynCardia's Notified Body, BSI has suspended CE 665479 due to nonconformities related to our Quality Management System.

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Recommended actions

EU Distributors, cease further distribution of the TAH-t until SynCardia communicates the CE Certificate suspension has been lifted and the supply chain has been reestablished.

Potential clinical effects

The above described problem has been assessed with regard to its clinical impact on devices already implanted. No new risk was identified and SynCardia will continue fulfilling its legal obligations as medical device manufacturer to support and monitor the clinical field.

Actions taken by SynCardia

SynCardia will, effective immediately, and for the foreseeable future, will no longer be able to support new accounts or new implants with TAH-t in the EU. This does not affect the patients that have been implanted prior to the date of this communication.

Actions to be taken by SynCardia

To mitigate unnecessary risk, no new products will be placed on the EU market. Products which are already placed on the market will be used to support already implanted patients ensuring a higher level of protection.

SynCardia Systems, LLC is diligently working to correct and close the nonconformities issued by our Notified Body. The suspension must be resolved by 19 Jun 2022 to prevent cancellation of the certificate.

We are also working with both existing and new suppliers in order to reestablish our supply chain, and to find solutions as soon as possible. However, this process will take longer than usual, particularly in view of the worldwide impact of COVID-19 on the global supply chain. The information available to date suggests that this situation could extend over the whole of 2022 or even into 2023.

Contact

If you have any questions or comments regarding this notice, please contact your SynCardia Regulatory Affairs Department @ regaffairs@syncardia.com

The applicable Competent Authorities will be notified of this action.

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Customer Acknowledgment Form – RA-1720 Rev 001

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:	