

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

SynCardia Systems, Freedom Driver System - Part May Fail Causing Device to Stop Working

Recall Class: Class I

Date Recall Initiated: August 7, 2015

Device: Freedom Driver Systems used with the SynCardia temporary Total Artificial Heart (TAH-t)

- Lot numbers:
 - 85978 (Serial Numbers 85978-001 through 85978-040)
 - 85979 (Serial Numbers 85979-001 through 85979-040)
- Manufactured from: November 3, 2014 to July 29, 2015
- Distributed from: November 10, 2014 to July 29, 2015
- Devices Recalled in the U.S.: 29

Use: The SynCardia Total Artificial Heart (TAH-t) is a mechanical replacement for a patient's heart. It is a pump that is implanted into the chest to replace the bottom half of a patient's heart (left and right ventricles). The device is sewn to the remaining top half of the patient's heart (atria). The Freedom Driver System is attached to the TAH-t pump and operates and monitors the device.

The TAH-t is used in patients at risk of imminent death from heart failure who are waiting for a heart transplant.

Recalling Firm:

SynCardia Systems, Inc.
1992 E. Silverlake Road
Tucson, AZ 85713

Reason for Recall: A specific part of the Freedom Driver drive mechanism may fail and cause the device to stop pumping. Patients do not receive any advanced warning that the device may fail. If it does fail, a red light located in the center of the driver, towards the top, will stay red and a loud continuous alarm will sound.

However, if the Freedom Driver stops pumping, the patient will lose consciousness almost immediately, which means that the warning light and alarm may not be helpful. The patient will likely experience serious injury or death if not immediately switched to a backup driver by a caregiver.

Public Contact: Customers with questions may contact SynCardia Systems at 866-480-1122, extension 1308, Monday through Friday, 7:30 AM – 5:00 PM, Pacific/Arizona Time or 866-771-9437, 24 hours per day, 7 days per week.

FDA District: Los Angeles District Office

More Information about this Recall:

On August 6, 2015, SynCardia Systems sent an Urgent: Medical Device Recall letter to their customers. SynCardia told customers they will notify all hospitals that have the affected drivers and replace the drivers with new ones. Additionally, SynCardia informed customers to:

- Notify any patients with an affected device and exchange the driver
- A SynCardia representative will assist with replacement and return of the product
- Return affected Freedom Drivers and complete the Recall Acknowledgement and Receipt Form attached to the letter.

About Class I Recalls

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program** (<https://www.accessdata.fda.gov/scripts/medwatch/>) online, by regular mail or by FAX.

<p>More in <u>Medical Device Recalls</u> (/MedicalDevices/Safety/ListofRecalls/default.htm)</p>
<p><u>2015 Medical Device Recalls</u> (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)</p>
<p><u>2014 Medical Device Recalls</u> (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)</p>