



**URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE**  
**SynCardia Freedom Drivers**

December X, 2017

Customer Name  
Device Name  
Street Address  
City, State, Zip Code

Dear Device Customer,

**1. Purpose Of This Letter**

SynCardia is making changes to the manuals and labeling of the Freedom Driver System Model No. 595000-001 that will strengthen existing warnings for users with regard to Freedom Driver drops, rough handling and exposure to liquid/debris. These labeling changes will enhance the safe use of the Freedom Driver System.

To reinforce these changes to the manuals and labeling of the Freedom Driver, SynCardia will conduct a Field Safety Corrective Action to contact pertinent Freedom Driver Customers. This Field Safety Notice details the issue, any potential risks and recommended steps.

Freedom Drivers are components of the SynCardia temporary Total Artificial Heart (TAH-t) System, which is indicated for use in transplant-eligible candidates at risk of imminent death from biventricular failure. Freedom Drivers are intended for use in and out of the hospital.

Serious injury or death could occur because of the failure of a Freedom Driver. Freedom Driver drops, rough handling or exposure to liquid/debris may result in the failure of a Freedom Driver so after such events, patients must switch to their backup Freedom Drivers.

**2. Reason for the Voluntary Field Safety Corrective Action**

SynCardia has updated the Freedom Driver System manuals and labeling to strengthen existing labeling content with regard to Freedom Driver drops, rough handling and exposure to liquid/debris.

The Freedom Driver System manuals have been updated as follows:



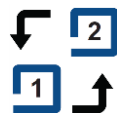
1. Advising patients to switch from their primary Freedom Driver to their backup Freedom Driver in the event their Freedom Driver is dropped, subjected to rough handling or exposed to liquid/debris.
  - a. Added more detailed information regarding the definition of rough handling.
2. Advising hospital clinicians, patients and their caregivers to clean the Freedom Driver and drivelines **ONLY** with a cloth lightly dampened with water.
3. Advising hospital clinicians to refresh patient and caregiver training at every clinic visit.

A new label was added to the Freedom Driver as discussed below:

1. A new label was added to the Freedom Driver containing two new symbols shown in **Figure 1**, in addition to the harmonized “Keep Dry” symbol. These two new symbols are defined in the *Freedom Driver System Operator Manual* in Chapter 8, List of Symbols. This label adds and strengthens an instruction that is intended to enhance the safe use of the device.



**Do Not Drop**



**Exchange if Dropped,  
Subjected to Rough  
Handling or Exposed  
to Liquid/Debris**

**Figure 1: New Symbols**

The updates to the warnings in the Freedom Driver System manuals and labeling will enhance the safe use of the Freedom Driver System.

SynCardia is conducting a voluntary Field Safety Corrective Action to reinforce these changes by informing Freedom Driver customers of the changes and ensuring that the clinical staff and patients review the changes and that the patients are trained on the new labeling.

### **3. Risk to Health**

If the Freedom Driver is dropped, exposed to liquid/debris or subjected to rough handling, it may sustain damage that will not allow it to provide life-sustaining functions as designed. In the event that a patient’s Freedom Driver is dropped, subjected to rough handling or exposed to liquid/debris, the patient must switch to the backup Freedom Driver.



**4. Actions To Be Taken By The Customer/User**

The clinical staff and Freedom patients must review changes to the manuals and labeling and Freedom patients must undergo training on the updated manuals and labeling.

The hospital must return the completed Acknowledgement and Receipt Form below to SynCardia.

**5. Product and Distribution Information**

A list of current Freedom patients affected by this notification at your site, according to our records, is included below for your information.

**6. Type of Action by the Company:**

SynCardia will provide the updated labeling for review and training as follows:

- *Freedom Driver System Operator Manual*
- *Freedom Driver System Guidebook for Patients and Caregivers*
- *Freedom Driver System Quick Guide*
- *Freedom Driver System Overview for Patients and Caregivers*
- *Freedom Driver System Overview for Clinical Operators*

Customer notifications will be included in all Freedom Discharge Kits for a period of one year to notify the customers of these changes in the labeling.

**7. Contact Information For Questions**

Mary Pat Sloan  
Senior Vice President Global Certification and Logistics  
SynCardia Systems, LLC  
1992 E Silverlake Rd  
Tucson, AZ 85713  
Direct +1-520-547-7470  
Monday-Friday 7:30 AM to 5:00 PM Pacific/Arizona time  
Hotline 24/7 +49 700 796227342  
[www.syncardia.com](http://www.syncardia.com)

The applicable Competent Authorities will be notified of this action.

SynCardia Systems, LLC  
1992 E. Silverlake Rd.  
Tucson, Arizona 85713  
Telephone: 520.545.1234  
Facsimile: 520.903.1782



Sincerely,  
Mary Pat Sloan

A handwritten signature in black ink that reads "Mary Pat Sloan". The signature is written in a cursive, flowing style.

Senior Vice President  
Global Certification and Logistics



**MEDICAL DEVICE FIELD SAFETY NOTICE RETURN RESPONSE**  
**Acknowledgement and Receipt Form**

**Immediate Action and Response are Required**

**FREEDOM DRIVERS**

Customer Name  
Street Address  
Town, State, Zip Code

**1. Confirmation**

I have read and understand the instructions provided in the SynCardia Field Safety Notice dated December X, 2017. Yes \_\_\_ No\_\_\_

**2. Instructions for Responding to Field Safety Notice on Freedom Drivers**

- 2.1 Please review **Table 1** below and confirm that the listed patients are being supported by Freedom Drivers at your site.
- 2.2 Please train the patients on the updates to the Freedom Driver manuals and labeling and document date of training for each patient in **Table 1**.
- 2.3 Fax a completed copy of the signed Acknowledgement and Receipt Form to SynCardia Systems, LLC, Attn: Danielle Davis, (Fax: +1-520-903-1782) or scan and e-mail to [ddavis@syncardia.com](mailto:ddavis@syncardia.com).
- 2.4 If you have any questions, please contact Mary Pat Sloan by telephone at +1-520-547-7470 or by email at [msloan@syncardia.com](mailto:msloan@syncardia.com).

SynCardia Systems, LLC  
 1992 E. Silverlake Rd.  
 Tucson, Arizona 85713  
 Telephone: 520.545.1234  
 Facsimile: 520.903.1782



**Table 1: Freedom Driver Patient Information**

Assigned Freedom Patient ID	Date Training Completed

<b>Print Name of Hospital Representative</b>	
<b>Title</b>	
<b>Telephone</b>	
<b>Email address</b>	

<b>Signature</b>	
<b>Date</b>	