SynCardia Systems, Inc.
1992 E. Silverlake Rd.
Tucson, Arizona 85713
Telephone: 520.545.1234
Facsimile: 520.903.1783

Urgent Field Safety Notice

Repair of Hole/Tear in Cannulae in a Patient Implanted with the SynCardia temporary Total Artificial Heart (TAH-t)

February 3, 2023

Dear Total Artificial Heart Clinician:

You are receiving this notification as a health care provider of a patient implanted with the SynCardia temporary Total Artificial Heart (TAH-t) to alert you of the potential for a hole or tear that may occur in the pneumatic cannulae of the TAH-t and what actions should be taken in the event of occurrence. It is possible for a cannulae to have more than one hole or tear in its lifetime. To date, there have been zero reported Serious Adverse Events associated with a cannula hole or tear, but SynCardia has received 93 complaints regarding cannula tears as of October 24, 2022.

The potential risk associated with a cannula hole/tear is reduced cardiac output. The Freedom Driver is designed to annunciate a permanent alarm if the cardiac output is below 3.5 L/min alerting the patient to the potential harm.

Cannula holes and tears have most often occurred at the distal end of the cannulae where the CPC Connectors are attached to connect the cannulae to the drivelines of either the Companion 2 or the Freedom portable driver. On occasion, a tear can occur in different areas. See **Figure 1**. The tear may be accompanied by airflow hissing or whooshing sounds.

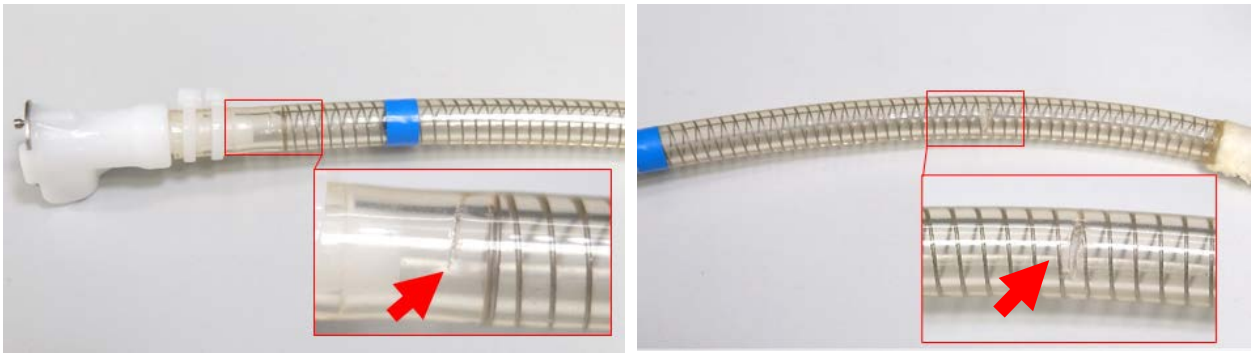

Figure 1 – Examples of Hole/Tear

Prior to a hole/tear occurring, train the patient to properly inspect the cannulae for holes/ tears and to recognize the signs of a tear/hole.

If a hole/tear occurs, the patient should immediately call the hospital to arrange for repair.

For Clinicians Only

While SynCardia has not validated the below instructions, there have been literature articles[i][ii] on this method to repair a cannula tear by removing the damaged cannula segment. The repair requires a backup Companion 2 or Freedom portable driver, a secondary driver driveline connector, zip ties, and high-leverage cable cutters as shown in **Figure 2**. The repair should be implemented quickly by at least two operators following the instructions below. One operator will prepare and operate the backup driver. A second operator will cut and reconnect the cannula.

1. Inspect both cannulae for any sign of a tear, hole, or cut, which can be visually detected or detected by listening for a hissing sound or whooshing of air.

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2. Prepare a backup driver with an appropriate secondary connector attached to the affected driver driveline (left or right, as applicable). Power on the selected backup driver and keep it on standby for the next repair steps.
3. Using a high-leverage cable cutter, see **Figure 2**, cut the cannula through the coil wire (if applicable) slightly distal to the tear to minimize the loss of cannula length. Insert a secondary connector barb (connected to the powered backup driver) into the cut cannula. Secure the cannula to the new connector with zip ties.
4. Disconnect the other undamaged cannula from the primary driver and reconnect it to the backup driver. A diagram that depicts the cannula repair procedure is shown in **Figure 3**.
5. Change backup driver from standby to run with the correct settings for the patient.

Figure 2 – Representative High-Leverage Cable Cutter

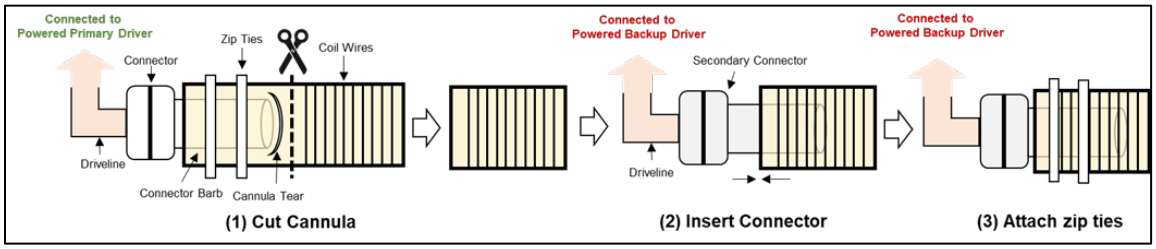

Figure 3 – Cannula Tear Repair Procedure

Please complete and return the enclosed response form as soon as possible and provide the Letter to Patient to all of your TAH-t patients. If you have any questions, please call your SynCardia Customer Support Manager or 1-866-480-1122.

The appropriate Competent Authorities have been made aware of this Urgent Field Safety Notice.

Adverse events experienced with the use of this product should be reported to SynCardia by email (intl.complaints@syncardia.com) or 24-hour emergency line (1-866-771-9437) and may also be reported to the local and appropriate Competent Authority.

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[i] Spiliopoulos, Sotirios et al. "Repair of left ventricular driveline tear in a SynCardia-total artificial heart patient." Journal of Cardiothoracic Surgery. 2014;9:7. doi:10.1186/1749-8090-9-7

[ii] Shah, Keyur B. et al. "Fracture of the total artificial heart pneumatic driveline after transition to the portable driver." The Journal of Heart and Lung Transplantation. 2014. Volume 32, Issue 10, 1041-1043

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Customer Acknowledgement Form

Urgent Field Safety Notice

Repair of Hole/Tear in Cannulae in a Patient Implanted with the
SynCardia temporary Total Artificial Heart (TAH-t)

Please complete this Customer Acknowledgement 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 the notification

☐ I have read and understand the notification

Printed name of person	Facility/Business Name
Signature	Date:
Address and City	
Telephone:	
Date the notification was received:	

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SynCardia
A Picard Medical Company

Repair of a Hole/Tear in your Cannulae of the SynCardia temporary Total Artificial Heart (TAH-t)

Dear Total Artificial Heart Patient:

You are receiving this notification as a patient's caregiver or patient implanted with the SynCardia temporary Total Artificial Heart (TAH-t) to alert you of the potential for a hole or tear that may occur in the pneumatic cannulae of the TAH-t and what actions should be taken in the event of occurrence. The pneumatic cannulae of the TAH-t provides pressurized air to the TAH-t, driving device operation See **Figure 1**. To date, there have been zero reported Serious Adverse Events associated with a cannula hole or tear but SynCardia has received 93 number of complaints regarding cannula tears as of October 24, 2022.

Cannula holes and tears have most often occurred at the end of the cannulae where the CPC Connectors are attached to connect the cannulae to the drivelines of either the Companion 2 or the Freedom portable driver. On occasion, a tear can occur in different areas. See **Figure 2.** The tear may be accompanied by airflow hissing or whooshing sounds.

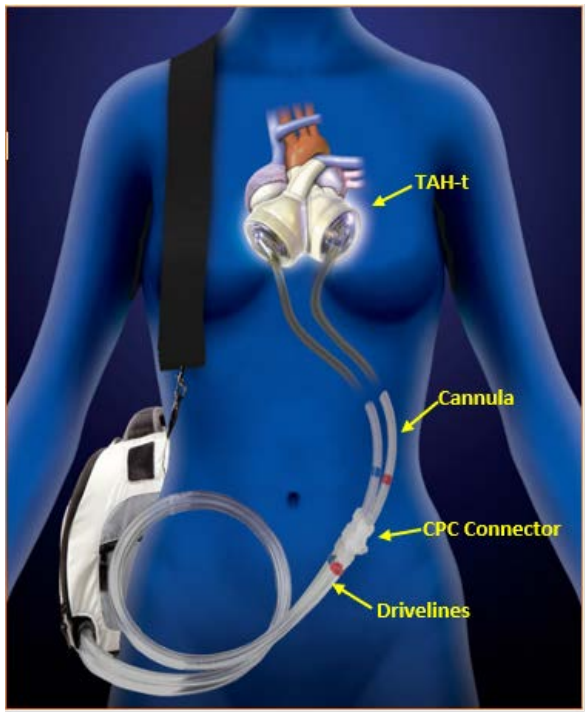

Figure 1 – TAH-t System

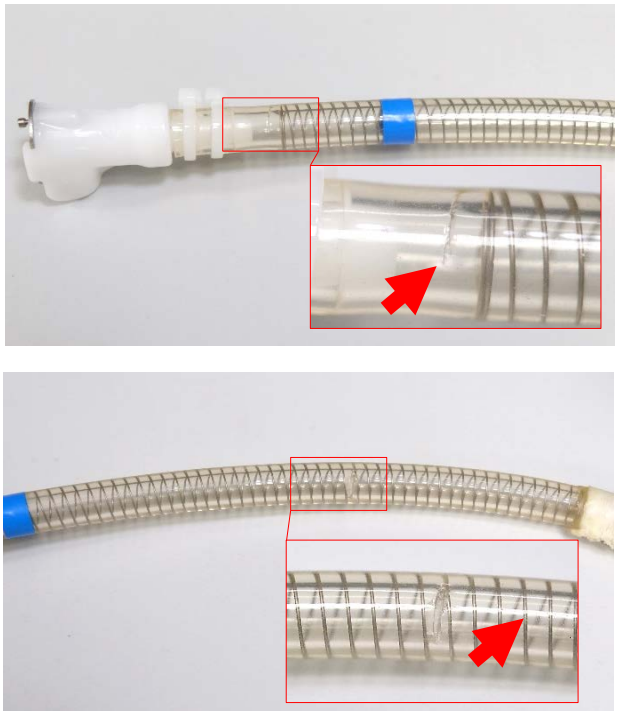

Figure 2 – Examples of Hole/Tear

Inspect both cannulae of the TAH-t system visually and by feeling the length of the cannulae for any holes and/or tears daily.

If a hole/tear occurs: **IMMEDIATELY** call the hospital to arrange for repair.