



To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**

**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**

**Director General of Engineering Affairs, MOH**

**Director General of Royal Hospital**

**Director General of Khoula Hospital**

**Director General of Medical Supplies (MOH)**

**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**

**Hospital Director (Al Nahda Hospital)**

**Hospital Director (Al Massara Hospital)**

**The Head of Medical Services in SQU Hospital**

**The Head of Medical Services in Royal Oman Police**

**The Head of Medical Services in Ministry of Defence**

**The Head of Medical Services in The Diwan**

**The Head of Medical Services in The Sultan's Special Force**

**The Head of Medical Services in Internal Security Services**

**The Head of Medical Services in Petroleum Development of Oman**

**The Head of Medical Services in LNG Oman**

**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No 53 dated 27/3/2023 Regarding NCMDR  
FSCA of SynCardia temporary Total Artificial Heart (TAH-t) from (mfr: SynCardia Systems Inc.).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 53/ 2023

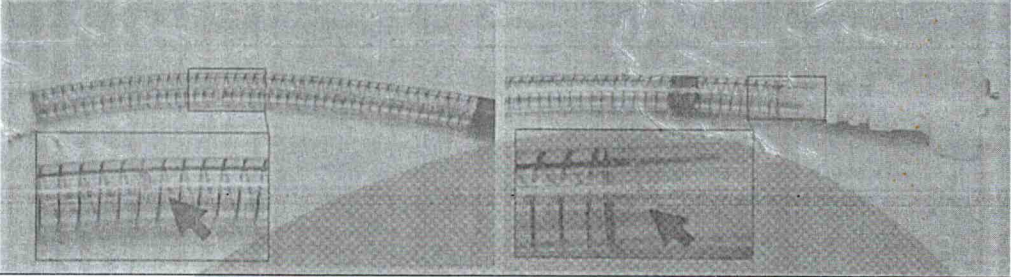
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27 -03-2023

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Moving Forward  
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رؤية عمان  
2040  
Oman Vision

### Field Safety Corrective Action of SynCardia temporary Total Artificial Heart (TAH-t) from SynCardia Systems Inc.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=18465">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=18465</a>
Product	SynCardia temporary Total Artificial Heart (TAH-t).
Description	Artificial heart.
Manufacturer	SynCardia Systems Inc.
The affected products	SynCardia temporary Total Artificial Heart (TAH-t).
Reason	Potential for a hole or tear that may occur in the pneumatic cannulae of the TAH-t.
Action	1. 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. 2. Refer to instructions for clinicians only in the attached FSN. 3. Contact the local agent for remedial action.
Product Image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaye  
Director General



## Urgent Field Safety Notice

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

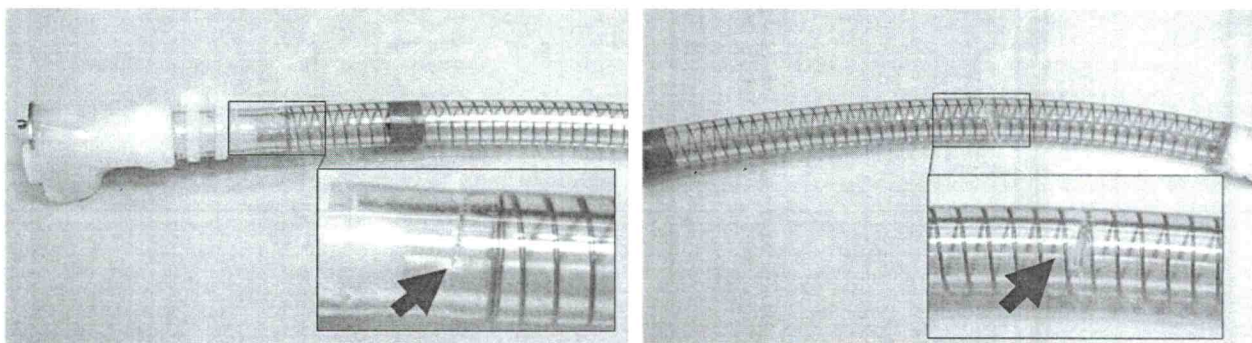
February 17, 2023

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**

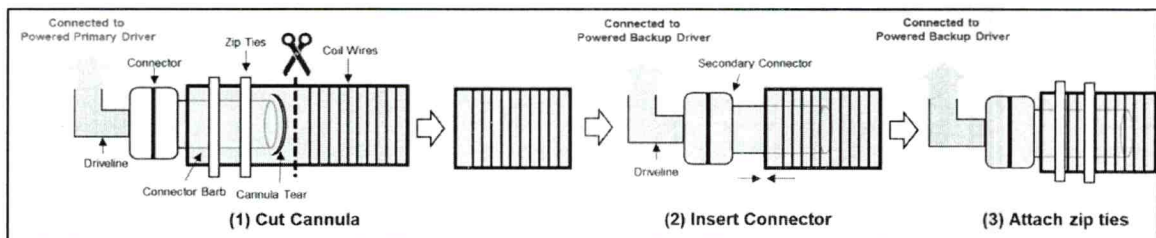
While SynCardia has not validated the below instructions, there have been literature articles<sup>[1][2]</sup> on this method to repair a cannula tear by removing the damaged cannula segment. The repair requires a backup Companion 2 or Freedom portable driver, a secondary driver driveline connector, 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.

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](mailto: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, the Saudi Food and Drug Authority (SFDA) at <https://www.sfda.gov.sa/ar>, or via telephone at: 0118806000-0112038222.

<sup>[1]</sup> 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

<sup>[2]</sup> 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](mailto:regaffairs@syncardia.com)

Please check the box to acknowledge the notification

I have read and understand the notification

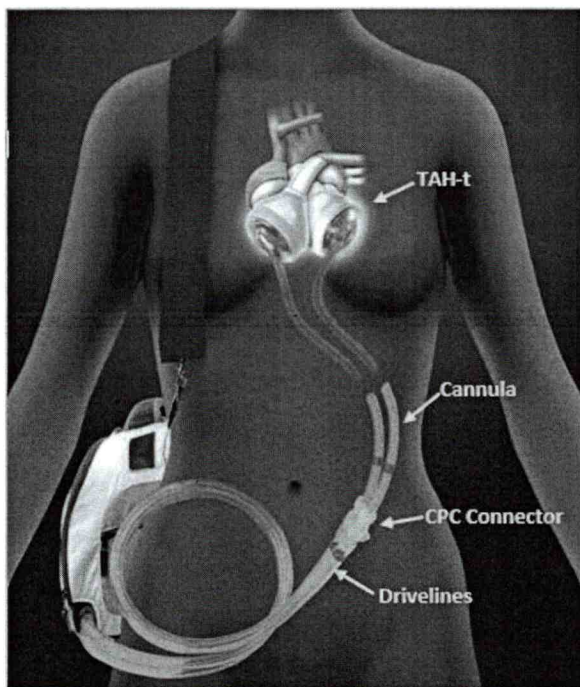
Printed name of person	Facility/Business Name
Signature	Date:
Address and City	
Telephone:	
Date the notification was received:	

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

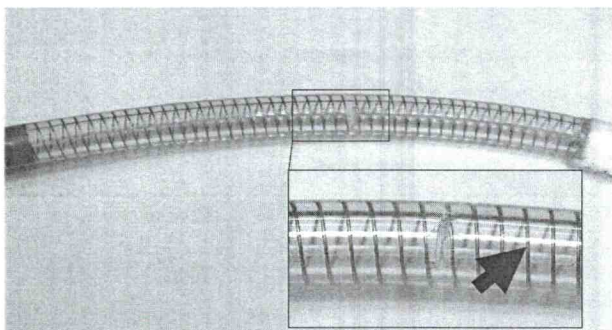
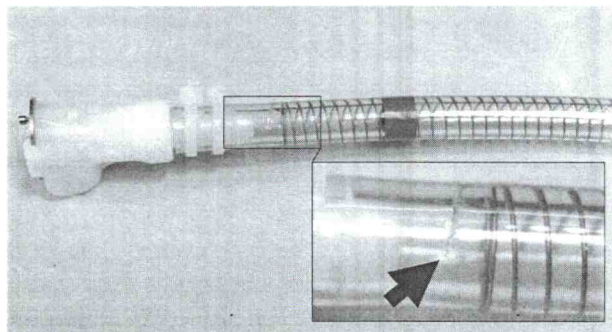
Dear Total Artificial Heart Patient:

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.