



رقم المحفوظات: ٢٠١٣/١/٢٤٤٠٤
رقم الصادر: ١٣/١/٢٤٤٠٤
بيروت، في: ٣ فبراير ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Implant, SynCardia temporary Total Artificial Heart (TAH-t)
with Bileaflet Valves

الجهاز المعني بالمتابعة:

- Implant, SynCardia temporary Total Artificial Heart (TAH-t) with Bileaflet Valves
- Trade Mark: SynCardia Systems Inc
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة

والتي تشير الى سحب الصنف المذكور أعلاه ، لذلك نرجو منكم تعميم هذه التوصية على جميع
المستشفيات المعنية.

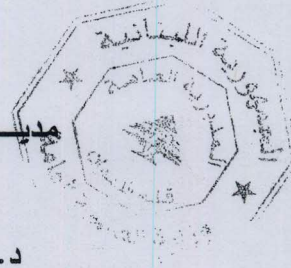
مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة

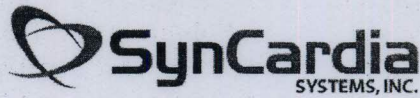
يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار



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



August 7, 2013

Urgent Field Safety Notice

**SynCardia temporary Total Artificial Heart (TAH-t) with Bi-leaflet Valves
RA-417**

Attention:

This letter is a notification that SynCardia Systems has removed the SynCardia temporary Total Artificial Heart (TAH-t) with bi-leaflet mechanical valves (P/N 550101-001) from the market.

The reason for the removal is that, in the EU post approval clinical study, examination of the left inflow valve of two explanted TAH-ts with bi-leaflet valves has revealed wear that is unacceptable to SynCardia Systems, Inc. There have been no reported patient adverse effects attributable to the TAH-t with bi-leaflet valves.

Please verify the disposition of each TAH-t with bi-leaflet valves that was shipped to you, including that any unused TAH-ts with bi-leaflet valves have been returned to SynCardia.

Please be advised that this notice will be provided to the appropriate Regulatory Agency.

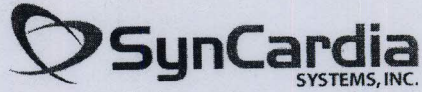
If you have any questions, please contact me by telephone at +1-520 545-1234 or +1-520-440-██████ or by email at ████████@syncardia.com.

As always,

██████████
Vice President of Global Communication & Logistics

SYNCARDIA SYSTEMS, INC. - STRICTLY PRIVATE

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



RETURN PAGE

Site: _____

INSTRUCTIONS:

1. Please review the list below and verify the disposition of each TAH-t with bi-leaflet mechanical valves. Please sign, date and return the form as directed in instruction 2 below to acknowledge receipt of this notification.
2. Fax a completed copy of the signed form to SynCardia Systems, Inc., Attn: [REDACTED], Staff Accountant (Fax: +1-520-903-1782) or scan and e-mail to [REDACTED]@syncardia.com.
3. If you have any questions, please contact [REDACTED] by telephone at +1-520 545-1234 or +1-520-440-[REDACTED] or by email at [REDACTED]@syncardia.com.

TAH-ts with Bi-leaflet Valves

Serial Number	Current Disposition

Form Completed by:

Printed Name

Signature

Title

Date