REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧١/٢٥
رقم الصادر: ١٢/١/٢٨٤٢٢
بيروت، في: ٢٩ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
SYNERGY Circulatory Support System

الجهاز المعني بالمتابعة:

- SYNERGY Circulatory Support System.
- Trade Mark: Circulite
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف المذكور أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

Museum Street - Hussein Mansour Blg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

CircuLite

CircuLite GmbH | Pauwelsstrasse 19 | 52074 Aachen, Germany

Urgent Field Safety Notice (FSN)

Product Name: SYNERGY® Circulatory Support System
FSCA-identifier: CLFSCA-001
Type of Action: Suspension of Implantation

Date: 27 July 2013

Attention: Physicians and Hospital Staff using the CircuLite SYNERGY Circulatory Support System

Details on affected devices:

SYNERGY Micro-Pump Kit (SIK 100)
Note: This kit is also part of the SYNERGY Implantation Kit (SIK 001)

Description of the problem:

Three instances of inflow cannula fracture have been reported to CircuLite. We are evaluating the root causes of those events now. Effective immediately, CircuLite is suspending implants of the surgical SYNERGY Circulatory Support System in Europe until further notice.

Patients with an implanted device may be at risk for a cannula fracture. In prior patients this has resulted in hemolysis and a need to stop and/or explant the pump, leaving patients without mechanical circulatory support.

Action Required:

1. Physicians are advised to suspend implant of the SYNERGY system in new patients.
2. Physicians are advised to inform patients of this Field Safety Notice.
3. Patients currently on device should be monitored as usual for any signs of low flow through the pump in the absence of a decrease in speed setting during routine follow-up exams (e.g., decreased current, hemolysis).
4. If low flow is suspected, obtain a chest x-ray and/or CT scan to evaluate the inflow cannula position and integrity.
5. If a cannula fracture is suspected, the pump should be stopped under medical supervision and a decision made as to whether or not to explant the pump.
6. A decision should be made as to whether the patient requires support with another form of mechanical circulatory support or can be managed medically. If the pump is explanted, blood should be aspirated from the inflow cannula and outflow graft to extract any thrombus that may have formed during the period of pump stop. The outflow graft can be ligated near its insertion with the subclavian artery. The inflow cannula can be occluded using a vascular occlusion device.

7. As usual, patients should be instructed to return to the hospital for controller alarms or if they exhibit signs of hemolysis such as red tinged or dark colored urine.
8. Existing patients will continue to be supported. At this time, devices that are serving as backup for patients who were previously implanted may be retained. Unnecessary devices should be returned to the manufacturer.
9. Immediately inform a CircuLite Clinical Specialist or the contact person listed on this letter if any abnormalities in the pump or patient are observed.
10. Acknowledge receipt of this Field Safety Notice to verify that you have been made aware of this issue by signing the acknowledgement form and returning it to the contact person identified below.

Distribution of this Field Safety Notice:

Please share this information with any staff that may use these products, especially patients who have been treated with the SYNERGY Circulatory Support System Inflow Cannula. Please maintain awareness on this notice.

Contact reference person:

If you have any questions concerning this notice, please contact:

Cajetan von Koenig
Director Marketing, European
Mobile: +49 151 2033 5106
cvkoenig@circulite.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Regards,

[redacted]

Director, Regulatory Affairs Europe

Please provide this Urgent Field Safety Notice (FSN) to any Cardiothoracic Surgeons, Cardiologists or other clinicians at your facility who are treating patients with an implanted SYNERGY Circulatory Support System.