RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨/٢٥
رقم الصادر: ٩٧/١/٢٠٠٣
بيروت، في: ١٢ شباط ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Implants, Non active, Peripheral Vascular Stents Peripheral Vascular Sten. Zilver PTX Drug-Eluting Peripheral Stent.

الجهاز المعني بالمتابعة:

- Implants, Non active, Peripheral Vascular Stents Peripheral Vascular Sten. Zilver PTX Drug-Eluting Peripheral Stent.
- Trade Mark: Cook Medical
- Local Representative: EMEC-ETCO Medical equipment company

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد اعلاه 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

الجمهورية اللبنانية
المديرية العامة
وزارة الصحة العامة

مدير عام الصحة
د. وليد عمار

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

COOK

Cook Ireland Limited
O'Halloran Road,
National Technological park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

Urgent Field Safety Notice

Commercial name of the affected product: Zilver PTX Drug-Eluting Peripheral Stent
FSCA-identifier: 2013C0003 (linked to Field Safety Notice issued in December 2012, FSCA-identifier: 2012C0005)
Type of action: Field Safety Corrective Action

Date: 19/04/2013

Attention: Chief Executive

Details on affected devices:

Zilver PTX Drug-Eluting Peripheral Stent
Catalogue Number: ZIV6*****PTX
Lot Number: *Please see attached list for the affected products/lots.*

Description of the problem:

Cook Medical has received a number of complaint reports relating to the delivery system for the Zilver PTX Drug Eluting Stent (13 complaints with an occurrence rate of 0.043%; two occurrences were considered serious adverse events) involving fractures of the delivery system inner catheter after stent deployment, and separation of the inner catheter tip section. In December 2012, Cook issued a Field Safety Notice (FSCA-identifier: 2012C0005) to customers advising of the potential risk of tip/inner catheter separation, but no root cause had been established at that time. Since December 2012, Cook Medical has responded to complaint reports by carrying out an in-depth investigation to better understand the root cause and the risk to patients of these tip separations.

As a result of our investigation, Cook Medical is initiating a voluntary withdrawal as we have determined that there is a higher than expected potential of inner delivery catheter breakage due to inconsistencies in the catheter manufacturing process. This withdrawal is intended to address the patient risks that may be associated with this potential occurrence.

Please note:

- This is a potential failure mode of the delivery system and does not affect the safety or efficacy of the implantable stent. Previously implanted stents are not affected by this withdrawal.
- This notice relates only to the ZILVER PTX Drug Eluting Peripheral Stent delivery system. Any ZILVER FLEX and other bare metal stents from Cook Medical are not affected.

Our records indicate your facility has received Zilver PTX Drug-Eluting Peripheral Stents.

Advise on action to be taken by the user:

1. Please review the attached list and quarantine any affected product that remains in your stock.
2. Immediately collect all remaining unused products. The remaining unused products should be returned as soon as possible. Please contact Cook Customer Services to obtain a Return Authorisation number for the return shipment.

Send the removed devices to:

Cook Ireland Ltd.
O'Halloran Road
National Technology Park
Limerick
IRELAND

Please ensure to mark the Return Authorisation number you have received from Cook Customer Services on the outside of the shipping carton.

Credit will be provided for the returned devices.

3. Please complete the attached Reply Form, which lists the product and lot numbers affected and return via email to **European.Complaints@CookMedical.com** or alternatively by fax to Cook Ireland marked for the attention of European Complaints / Customer Quality Assurance soon as possible to +353 61334441.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Contact reference person:

Emmett Devereux,
Director of Quality and Regulatory Affairs
COOK Ireland,
O'Halloran Road,
National Technology Park,
Limerick,
IRELAND.

Or

Annemarie Beglin
Customer Quality Supervisor,
COOK Ireland,
O'Halloran Road,
National Technology Park,
Limerick,
IRELAND.
tel +353 61 334440
fax +353 61 334441

Should you have any questions, please feel free to contact us for more information (e-mail: **European.Complaints@CookMedical.com**, phone: +353 61 334440).

We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter. We look forward to your response.