

REPUBLIC OF LEBANON

MINISTRY OF PUBLIC HEALTH

The Director General



الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٤٨/٢٥
رقم الصادر: ١٢/١/٢٥٢٣٧
بيروت، في: ٢١ تموز/أول ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Implants, non active, peripheral vascular stents. 200mm EverFlex self-expanding peripheral stent with Entrust delivery system.

الجهاز المعنى بالمتابعة:

- Implants, non active, peripheral vascular stents. 200mm EverFlex self-expanding peripheral stent with Entrust delivery system.
- Trade Mark: Ev3, Inc.
- Local Representative: Allied Medical S.A.L.

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى خلل في عمل الصنف الوارد أعلاه،
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





URGENT FIELD SAFETY NOTICE

EverFlex™ Self-expanding Peripheral Stent with Entrust™ Delivery System

[Date]

Attention: Risk Management Director and OR Materials Management
(Please forward this communication to all surgeons, surgical personnel, and any other potential users of the product.)

Re: Removal from the market of the 200mm EverFlex™ Self-expanding Peripheral Stent with Entrust™ Delivery System

Dear EverFlex Entrust Customer:

The purpose of this letter is to advise you that Covidien is conducting a Field Safety Corrective Action (FSCA) of the 200mm EverFlex™ Self-expanding Peripheral Stent with Entrust™ Delivery System because of reported deployment issues. Our investigation of field complaints has determined that the 200mm EverFlex Entrust have a higher rate of stent deployment difficulties in tight lesions or tortuous anatomy. Only the 200mm stent length EverFlex Entrust is involved in this corrective action.

The products being removed are associated with product codes:

EVX35-06200120
EVX35-06200150
EVX35-07200120
EVX35-07200150
EVX35-08200120
EVX35-08200150

No other EverFlex Entrust products are affected. The product code and lot number are printed on the primary and secondary package labeling.

Our records indicate that you have received product from one or more of the affected lots. Please review your inventory and perform the following action.

REQUIRED ACTIONS:

- 1. Immediately quarantine and discontinue use of the affected devices.**
- 2. Please return affected product as follows:**

- Please complete the attached Verification Form in its entirety. Fax the completed Form to the fax number or email address stated on the form. If you do not have any units in your inventory, simply return the Verification Form indicating you have zero (0) units. Upon receiving your form, Customer Service will be contacting you to organize the return of your products. You will receive credit for returned products.
- Please forward this letter to all colleagues within your organisation who need to be aware of it or to any organisation/persons where the potentially affected devices have been transferred.
- Your response is vital to our monitoring of the effectiveness of this FSCA. Please complete the attached Verification Form and return to Covidien via the instructions provided above.
- Should you have additional questions regarding returns, replacement stock, credit, or on the product involved in this FSCA, please contact your Covidien Representative XXXX XXXXXX at xxx-xxx-xxxx.
- This action is being taken with the knowledge of the [add local Competent Authority]. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

To ensure timely removal of the affected product, it is important that we receive the Return Verification form with the affected inventory as soon as possible. Please return this information to us within 10 days of this notification. We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

Sincerely,

Frank DeFazio
Senior Director, Quality & Compliance

Vascular Therapies
Covidien
15 Hampshire Street
Mansfield, MA 02048
U.S.A

Attached: Verification Form