



رقم المحفوظات: ٤٧٩/٢٥  
رقم الصادر: ١٣/١/١٧.٢٥  
بيروت، في: ٢٠ أيار ٢٠١٢

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي

Vascular cannula and catheters, catheter introducer, Edwards expandable introducer sheath set.

الجهاز المعني بالمتابعة:

- Vascular cannula and catheters, catheter introducer, Edwards expandable introducer sheath set.
- Trade Mark: Edwards Lifesciences
- Local Representative:

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 المذكور أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة  
د. وليد عمار



Edwards

**URGENT – FIELD SAFETY NOTICE**  
**Edwards Lifesciences Expandable Introducer Sheath Set**  
**Model Number: 9610ES14**  
**Lot number: 59390915**  
**Ref: FCA-24**

Date: 6 Mar 2013

Attention: For distribution to Risk Management & Users of the Expandable Introducer Sheath Set

**Details on affected devices:**

*14F Edwards Expandable Introducer Sheath Set, Model number 9610ES14, Lot number 59390915/intended for use with the 23mm and 26mm SAPIEN 3 Commander Delivery System in the clinical investigation, Study #2012-07, Safety and Performance Study of the Edwards SAPIEN 3 Transcatheter Heart Valve*

**Description of the issue:**

Edwards has identified during internal testing that in some cases the 14F ESheath shaft may not expand as intended causing tearing at the liner. If this were to occur clinically, the torn liner creates a potentially rougher surface which may cause or contribute to a vascular complication during removal of the device from the patient.

Edwards has therefore decided to recall the above lot of the 14F expandable Introducer Sheath set.

This Field Safety Notice does not pertain to the valve implant and patients already implanted are not affected by this Field Safety Notice.

**Action requested:**

1. Our records show that you have received the affected Expandable introducer Sheath Set of lot 59390915. These devices should not be used. Please review and quarantine any affected inventory immediately. Please return all unused affected product from your inventory to Edwards.

An acknowledgment form is included to assist you in the review of your inventory. Once you have verified your inventory, please complete the attached acknowledgment form (even if you have no inventory) and fax it back to Pascal Lehmann at +41 22 787 4303 within three days of receipt of this Field Safety Notice. This is to confirm that you have reviewed this notice and have taken appropriate action.

Please contact Pascal Lehmann (+41 22 787 4447 or [Pascal\\_lehmann@edwards.com](mailto:Pascal_lehmann@edwards.com)) to obtain a Returned Goods Authorization number and replacement product.



Edwards

Please return all affected product to the following address,

Edwards Lifesciences AG  
Altsagenstrasse 14  
Altsagenstrasse 14 CH 6048  
Horw LU, Switzerland  
Phone 41.41.348.2121

2. The 16F Expandable Introducer Sheath Set, Model 916ES23 may be considered for use in place of the 14F Expandable Introducer Sheath Set, Model 9610ES14. The 16F device expands to a maximal diameter of 7.9mm when the 26mm Commander is passed through it. In comparison, the 14F device expands to a maximal diameter of 8.0mm. Hence, the use of the 16F Expandable Introducer Sheath Set rather than the 14F does not impact the risk associated with the transfemoral access approach.

**Transmission of this Field Safety Notice:**

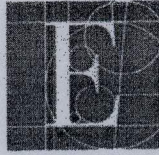
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

We sincerely regret the inconvenience caused by this action and greatly appreciate your immediate attention to this matter. If you have any questions that have not been answered by this letter, please contact your Edwards representative.

Yours sincerely,

Andleeb Arshad  
Regulatory Affairs Manager UK, Ireland and Nordics

Edwards has communicated this Field Safety Notice to all appropriate regulatory authorities



Edwards

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**Acknowledgment Form**

London King's College Hospital NHS  
Prof. Olaf Wendler  
Cardiac Catheter Suite  
King's College Hospital  
Denmark Hill  
SE5 9RS London

We acknowledge receipt of this Field Safety Notice involving the Edwards Lifesciences Expandable Introducer Sheath Set Model Number: 9610ES14, Lot number: 59390915  
We have reviewed and understand the information contained within and have taken the appropriate actions and disseminated this information to any affected staff, services and/or facilities.

**Please send completed signed form to Pascal Lehmann at +41 22 787 4303**

**Note:** Please indicate "NONE" if you have no Custom Kit inventory to return.

<u>Product Code / Model</u>	<u>Lot Number</u>	<u>Quantity Shipped From EW</u>	<u>UOM</u>	<u>Order Number</u>	<u>Date Shipped from EW</u>	<u>Number of units to be returned</u>	<u>Number of units used or discarded</u>	<u>RGA Number</u>
9610ES14	59390915	4		9297377	21/02/2013	4	0	9298155

Name (Print): \_\_\_\_\_

Signature: \_\_\_\_\_

Title and Department: \_\_\_\_\_

Contact Info.: / Tel. No. / Fax No. / Email: \_\_\_\_\_

Date: \_\_\_\_\_