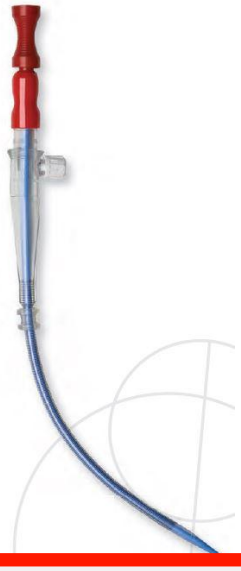
Urgent Field Safety Notice
Product Recall - Action Required

ATTENTION: Chief of Perfusion, Chief Nursing Officer, Director of Operating Room Services, Director of Intensive Care Unit, Director of Emergency Services, Risk Management



REASON FOR ACTION
Separation of Dilator Tips During Use

Edwards Lifesciences has identified a potential health risk to patients undergoing by-pass surgery when a Fem-Flex II™ arterial cannula is used.

Edwards Lifesciences has received five complaints in the last four months involving the separation of dilator tips on specific models of Fem-Flex II™ arterial cannula sizes 16, 18 and 20 French. Some of the reported events involved separation of the tip of the dilator required retrieval through an interventional radiologic procedure.

Complaints were first reported in December of 2013 for lots manufactured as early as March 2011. The investigation determined that the dilator made specifically for the 16, 18 and 20 French sizes presented a hazard during use. Based on the potential impact to patients, Edwards is recalling all 16, 18 and 20 French sizes of the Fem-Flex II™ arterial cannulae that have not expired.

Please note, only 16, 18 and 20 French sizes are affected, all other sizes of 8,10, 12 and 14 French sizes cannulae have not been affected by this issue.

Edwards is requesting that you quarantine and return any of this material you have in inventory.

POTENTIAL HAZARD
Due to the size of the fragments, there is potential for them to embolize. Since these devices are used in the femoral artery, an embolus may form in the distal extremity, which could result in a permanent injury.

AFFECTED PRODUCT (16, 18 and 20 French sizes only)
Our records show that you received one or more of the lots included in this field action. The current shelf life of these products is three years.

16 Fr.	18 Fr.	20 Fr.
DFEMII016AS	DFEMII018AS	DFEMII020AS
DIIFEMII016A	DIIFEMII018A	DIIFEMII020A
FEMII016A	FEMII018A	FEMII020A

WHAT TO DO NOW

Review this safety notice for product distributed to your location. Quarantine material and prevent from further use.

Complete acknowledgement form and contact number below to obtain Returned Goods Authorization number.

Returned completed form to fax number below.

Questions?
We encourage you to contact us with any questions or concerns:

Edwards Customer Service
Phone: xxx
Fax:**xxx**

Customer Service Hours
Monday – Friday
9:00 – 17:00

Edwards

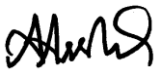
FEMII016AS	FEMII018AS	FEMII020AS

CUSTOMER INSTRUCTIONS

1. Please review your entire inventory for the femoral cannula product codes listed above.
2. **Please quarantine affected material at your site and return this product to Edwards**.
3. An acknowledgment form is included to assist you in the assessment of your inventory. On this form, every attempt has been made to provide you with a list of the affected inventory based on our records. We have included blank lines so that you may add any additional inventory that you may uncover during your assessment.
4. Once you have verified your inventory, please contact Edwards Customer Service at xxx (Country CS number) to obtain a Return Goods Authorization number and information about replacement product.
5. Please complete the attached acknowledgment form and fax it back to Edwards Customer Service at xxx (Country CS number) within three days of receipt of this Field Safety Notice. The return of this form allows us to confirm that you have reviewed this notice and have taken appropriate action.
6. This notice needs to be passed on to all those within your organization, or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact.
7. If you have questions that have not been answered by this letter, please call Edwards Customer Service at xxx, Monday - Friday from 9:00 to 17:00
8. **Please return affected product to the following address:**

Return product to:
Edwards Lifesciences
Attn: xxx
Attention: Recall Reference Number FCA-44, RGA #XXXXXX

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



Andleeb Arshad

Regulatory Affairs Manager UK, Ireland and Nordics

Edwards Lifesciences Ltd
Sherwood House, 78-84 London Road, Newbury, Berkshire UK RG14 1LA
Phone: 0870 606 2040 · Fax: 0870 606 250
Company Registered No. 3879325 VAT registered No. GB 724 5740 35

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