



Edwards

**URGENT FIELD SAFETY NOTICE
UPDATE TO REF: FCA-76**

ACTION REQUIRED

**Edwards Lifesciences LLC: Edwards Commander Delivery System Models
9610TF23, 9610TF26, 9610TF29**

August XX, 2016

ATTENTION: Risk Management and Users of the Edwards Commander Delivery System

Details on affected device:

Edwards Commander Delivery System Models 9610TF23, 9610TF26, 9610TF29

Dear Customer,

As already announced in our Field Safety Notice dated xxx May, 2016, Edwards has developed changes to the manufacturing process of the shaft at our supplier and have incorporated these changes into finished good manufacturing at Edwards.

The improved Edwards Commander Delivery System is available now in sufficient quantities to replace the remaining older version of the product in your inventory.

Our records show that you received one or more lots of affected product. An acknowledgment form is included to this Update of the Field Safety Notice to assist you in the assessment of your inventory. Please review your entire inventory for the lots listed in the Acknowledgment form. This form has been pre-populated with the inventory from our records.

Once you have verified your inventory, please complete the requested information in the attached acknowledgment form and fax it as soon as possible to Edwards Customer Service at 01 8211014. The return of this form allows us to confirm that you have reviewed this notice and have taken appropriate action. Once the acknowledgment form is received, an Edwards representative will contact you in the event there are products that need to be returned in order to coordinate the replacement of affected finished goods.

If you have any questions or concerns regarding this Update of Urgent Product Notification, please do not hesitate to contact your Edwards Clinical Specialist.



Edwards

Sincerely,

A handwritten signature in black ink, appearing to read 'Andleeb Arshad'.

Andleeb Arshad

Regulatory Affairs Manager UK, Ireland and Nordics

This Update of the Urgent Field Safety Notice has been communicated by Edwards Lifesciences to the relevant competent authorities.



**Edwards
Acknowledgment Form**

**THE URGENT FIELD SAFETY NOTICE
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**ACTION REQUIRED
Edwards Commander Delivery System Models 9610TF23, 9610TF26,
9610TF29**

Ship to Number (column B)
«Ship_to_Name» (column D)
Attention: Director O.R./Department Cardiac Surgery
«Add_1», «Add_2»
«City», «State»
«Zip», «Country»

Please complete as soon as possible the information below and FAX the completed form to Edwards Customer Service at 01 8211014
EW Customer Service will contact you in case products to be returned and will provide you RGA number and all additional required information.

Note: Please indicate "NONE" if you do not have any inventory to return.

Reference model	Lot Number Delivery System	Associated Kit Lot Number(s)	Qty Shipped from EW	Number of Units used	Number of Units to be Returned

Hospital / Location (Print): _____

Name (Print): _____

Title and Department: _____

Contact Information
Tel.No/Fax No /Email: _____

Signature: _____ Date: _____



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