



Edwards

**URGENT FIELD SAFETY NOTICE  
UPDATE TO REF: FCA-53**

**ACTION REQUIRED**

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

August 20, 2015

**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,

Edwards is updating its February 2015 'Urgent Field Safety Notice (FSN), ref: FCA 53, involving Edwards Commander Delivery Systems (23mm, 26mm, 29mm) used with the SAPIEN 3 valve.

An improved delivery system is available that was made specifically to address the valve alignment issues detailed in FSN ref: FCA-53. A section of the balloon shaft has a rougher surface finish requirement, which enhances the ability of the handle to engage with the balloon shaft and not slip during the fine adjustment step of valve alignment. The design specification for engagement force was increased and a surface roughness specification was added.

Furthermore, changes have been made to the handle appearance. The color of the handle is now white opaque and not clear gray as in the previous model iteration. In addition, the warning marker on the balloon catheter is now a white band and not yellow as in the previous model iteration. These changes are not related to the valve alignment issues described in FSN ref: FCA-53.



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These additional changes do not affect the existing IFU or current training recommendations.

Edwards will replace any remaining older version of the Edwards Commander Delivery System in your inventory with this new improved version.

Our records show that you received one or more lots of affected product. An acknowledgment form is included to this 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 xxx. The return of this form allows us to confirm that you have reviewed this notice and have taken appropriate action. EW Customer Service will contact you in case there are products to be returned and will provide you with RGA number and all additional information that is necessary.

In addition, as soon as the completed acknowledgment form is received in Edwards, your Edwards representative will contact you and schedule a visit to perform the replacement of the 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.

This Update of the Urgent Product Notification has been communicated by Edwards Lifesciences to all relevant regulatory authorities.

Sincerely,

Momchil Blagoev  
Director Regulatory Affairs EMEA  
Edwards Lifesciences



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**Acknowledgment Form**

**THE URGENT FIELD SAFETY NOTICE  
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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 XXX.

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 Kit	Lot Number Delivery System	Qty Shipped from EW	Number of Units used	Number of Units to be Returned

RGA Number: \_\_\_\_\_

Hospital / Location (Print): \_\_\_\_\_

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

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

Contact Information

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

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

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