URGENT PRODUCT NOTIFICATION ACTION REQUIRED

Edwards Lifesciences LLC

Edwards Commander Delivery System Models 9610TF23, 9610TF26, 9610TF29
REF: FCA-53

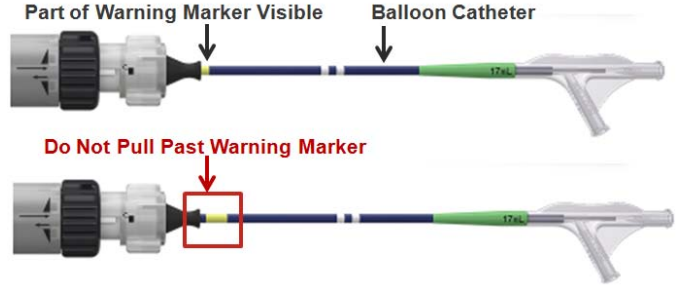
February 10, 2015

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

Details on affected device:
Edwards Commander Delivery System Models 9610TF23, 9610TF26, 9610TF29

Description of issue:
Edwards has learned that the Balloon Lock mechanism on the handle of the Edwards Commander System may not fully engage to the balloon catheter during the Fine Adjustment part of the Valve Alignment procedure. This has the potential to result in the inability to position the valve between the Valve Alignment Markers. Deploying the valve when it is not between the Valve Alignment Markers may result in suboptimal valve deployment. The troubleshooting maneuvers described below have resulted in successful deployments in most cases. If these maneuvers are not successful, the delivery system and valve can be retrieved into the eSheath and removed together from the patient and a new system should be utilized. Improper withdrawal of the delivery system through the tip of the eSheath can result in vascular injury and/or dislodgement of the valve from the delivery system. If the device cannot be successfully retrieved into the eSheath, the valve may be deployed in a non-target location.

Advice on action to be taken by user:
During the first stage of Valve Alignment, completely unlock the Balloon Lock and pull the balloon catheter straight back at the Y-connector until part of the Warning Marker is visible. Resistance may be experienced during this process. Do not pull past the Warning Marker. If the Warning Marker is fully exposed, adjust the Balloon Catheter so that only part of the Warning Marker is visible. Completely lock the Balloon Lock. Do not bend or torque the proximal end of the Balloon Catheter throughout the procedure.



Proceed with Fine Adjustment to center the valve between the Valve Alignment Markers. If the locking mechanism does not fully engage and additional Fine Adjustment is needed, completely unlock the Balloon Lock and rotate the Fine Adjustment Wheel away from you until part of the Warning Marker is visible, re-lock and proceed with Fine Adjustment.

If unable to position the valve between the Valve Alignment Markers with Fine Adjustment, completely unlock the Balloon Lock and rotate the Fine Adjustment Wheel towards you until the Fine Adjustment Indicator is fully extended. Then, manually pull the balloon catheter straight back at the Y-connector until the valve is between the Valve Alignment Markers and completely lock the Balloon Lock. Do not bend or torque the proximal end of the Balloon Catheter throughout the procedure.

If unable to complete valve alignment, the delivery system and crimped valve can be retrieved into the eSheath. Remove the entire system together with the eSheath. When withdrawing the delivery system with crimped valve, the delivery system must be coaxial to the tip of the eSheath to avoid vascular injury or dislodgement of the valve from the delivery system.

This Urgent Product Notification must be provided to all personnel responsible for preparing and or using the delivery systems during Edwards Transcatheter Heart Valve procedures within your organization (or any organization to where the affected devices have been transferred). Please acknowledge you have reviewed and understand this Urgent Product Notification by signing and dating this form. Please retain a copy for your records and forward your acknowledgement to the email address listed on Page 3 within 3 days of receipt of this Notification (February XX, 2015).

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

Sincerely,

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

URGENT- PRODUCT NOTIFICATION - ACTION REQUIRED

Edwards Lifesciences LLC

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

☐ I have informed all individuals at this site who are responsible for preparing and/or using the delivery systems, regarding the information contained in the above Urgent Product Notification related to Edwards Commander Delivery System Models 9610TF23, 9610TF26, 9610TF29 dated February 10, 2015:

_____
Signature -Responsible Site Personnel

_____
Name/Title

_____
Contact Info/Phone Number/E-Mail

_____
Site Name

COMMERCIAL SITES
RETURN THE SIGNED ACKNOWLEDGEMENT FORM BY EMAIL TO
xxxxxx@EDWARDS.COM
ATTN: