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URGENT FIELD SAFETY NOTICE

Edwards Lifesciences Commander Delivery System
Models 9610TF20, 9610TF23, 9610TF26, 9610TF29
Reference: FCA-123

Balloon Tears - ACTION REQUIRED

[DATE OF LETTER]

To: <<Customer Name>>
<<Customer Address>>
<<Customer City, State, Postal Code>>
<<Customer Country>>

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

Details on affected device:
Edwards Commander Delivery System Models 9610TF20, 9610TF23, 9610TF26, 9610TF29

Dear Customer,

Edwards Lifesciences would like to advise you of action to be taken by users of Edwards Lifesciences Commander Delivery System, models 9610TF20, 9610TF23, 9610TF26, 9610TF29.

Description of the Problem:
Edwards has received reports of balloon tears occurring during the valve alignment step with the Commander Delivery System. The observed complaint rate for this issue is approximately 0.14% based on the global experience with the device. The incidence of serious events related to this issue is approximately 0.02%, typically resulting from inability to fully inflate and/or difficulty removing the Delivery System, such as valve malposition with or without embolization, non-target deployment, vascular injury, significant bleeding, and/or need for surgical intervention to prevent permanent injury or death.

A thorough investigation of these reports concluded balloon tears typically occur when there is significant tension in the delivery system during valve alignment. Tension can be

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encountered if valve alignment occurs in a non-straight section of the vasculature or if the balloon is not adequately evacuated during device preparation.

In order to avoid significant tension, valve alignment should occur in a straight section of the vasculature. For transfemoral cases, a CTA of the chest-abdomen-pelvis may be necessary to properly assess the ascending and descending aorta. This assessment ensures a straight section is available for valve alignment.

Edwards advises to follow the guidelines and instructions provided in the Edwards SAPIEN 3 Commander delivery system training materials for device preparation and device use highlighted below. The IFU is being updated to also include these steps.

- Ensure there is no residual fluid left in the balloon during preparation and avoid overfilling the balloon during de-airing to prevent potential valve alignment difficulty.

- Execute valve alignment in a straight section of the aorta. Utilizing alternate fluoroscopic views may help with assessing curvature of the anatomy.

- If excessive difficulty is encountered when performing valve alignment, this may be an indication that alignment is being attempted in a non-straight section of the vasculature where alignment may not be safely achieved. In these cases, repositioning the delivery system to a different straight section of the aorta and relieving compression (or tension) in the system will be necessary (see Figure 1).

If manoeuvers are not successful and severe difficulty is still encountered, discontinue attempts to align the valve in order to prevent device damage and remove the system as a single unit while maintaining guidewire position.

Figure 1 illustrates instances of compression/ tension in the system during the procedure:

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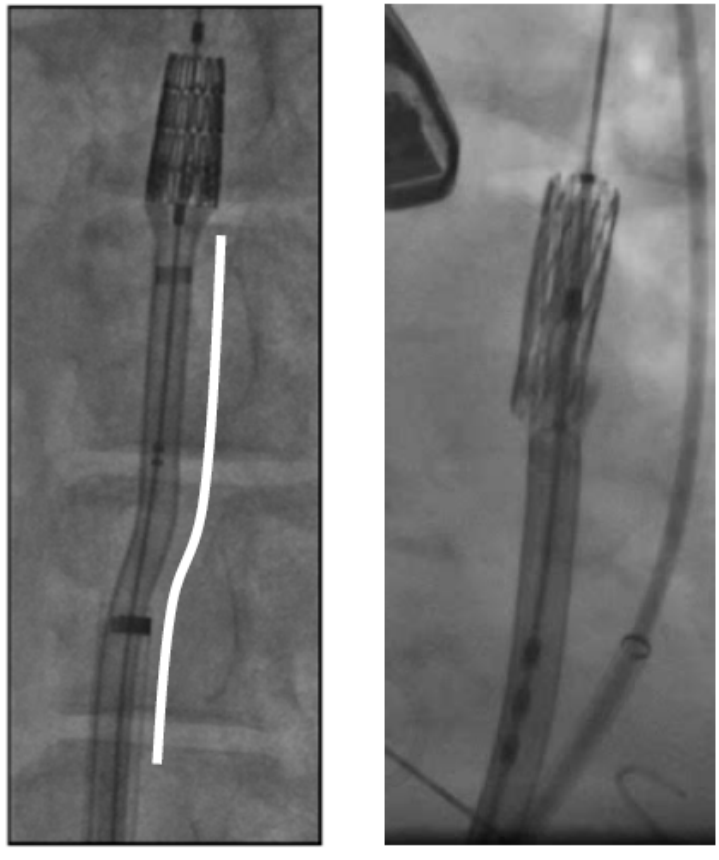

Figure 1: Delivery system flex shaft compression (Left) and valve diving (Right).

Action to be taken:
At this point in time, there is no action necessary other than completing the acknowledgment form included with this Field Safety Notice. Please review the Acknowledgment form, sign and date it, and return it to your Edwards Clinical Representative or FAX/email it as instructed on the form attached.

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

Sincerely,

Walt Wiegand
VP Quality, Transcatheter Heart Valves
Edwards Lifesciences

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

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Acknowledgment Form

[DATE OF LETTER]

This acknowledgement form confirms that we understand the information in the Urgent Field Safety Notice dated [DATE OF LETTER] regarding Commander Delivery Systems, Models 9610TF20, 9610TF23, 9610TF26, 9610TF29. We have shared this information with all appropriate clinical staff at our institution. We have also made the information available to personnel who may use these devices, as a part of continuing communication and training.

☐ I confirm receipt of the Field Safety Notice and that I read and understood its content.

Hospital Name:_____

Hospital Address: _____

Printed Name of Person Responding: _____

Title:_____Department:_____

Telephone: _____ Fax: _____ Email:_____

Signature: _____ Date:_____

Please email or fax this acknowledgement form to the attention of:

Customer Service

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