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# URGENT FIELD SAFETY NOTICE – ACTION REQUIRED

## Cardioband Mitral / Tricuspid Valve Reconstruction System (VSU04001 / VSU07001)

## Reference: FCA-151

<DD MMM YYYY>

<Physician Names>
<Hospital Name>
<Address>
<City/state/country/zip>

**RE: Cardioband Mitral/Tricuspid Valve Reconstruction System IFU**

Dear <Physician Names>,

**Details on affected devices:**

This voluntary notice is being provided to inform you of important updates to the Instructions for Use (IFU) for the Cardioband Mitral/Tricuspid Valve Reconstruction Systems, affecting the IFU included with the following product number: VSU04001 (Cardioband Mitral Delivery System) and VSU07001 (Cardioband Tricuspid Delivery System).

**Description of the problem:**

A higher than expected rate of coronary artery injury events has been observed in association with the use of the Cardioband Mitral/Tricuspid Valve Reconstruction System, approximately 5.7% overall. The majority of these events have occurred as a result of direct interaction between the anchors of the Cardioband device and coronary arteries running adjacent to the valve annulus, identified either during anchor deployment or following band contraction. Other events are related to vessel remodeling with no direct anchor and vessel interaction, which may occur following contraction of the band. All events were identified during the Cardioband procedure and were successfully addressed through immediate medical intervention. The required intervention in the majority of reported cases was balloon dilation or stenting of the impacted coronary artery. Close evaluation of these events in comparison with current labeling identified opportunities to enhance existing warnings and instructions related to vessel injury avoidance.

**Affected Product:**

Your current inventory of product is acceptable and safe for use. There is no need to return any product. Patients with the Cardioband device successfully implanted are not affected by this action. Your Edwards representative can answer any questions you may have regarding the IFU updates,

prior to the availability of the revised IFU in the packaged material. Once approved and translated, the updated IFU will be provided with future product shipments.

**Advice on action to be taken by the user:**

Preventative measures to reduce likelihood of vessel damage include:

- Consistent utilization of a guidewire in coronary artery in order to clearly visualize vessel throughout the procedure.
- Perform a coronary angiogram prior to first anchor deployment
- Verify the proximity of the coronary artery to target anchor position throughout the procedure.
- Perform a final coronary angiogram, before disconnecting delivery system from implant.

The Instructions for Use (IFU) are being revised to include clarification of the procedural steps and warnings related to vessel injury and are awaiting notified body approval. Although these details are missing from the current IFU, the instructions have been incorporated in physician training materials. As such, all users will be trained or retrained before use of the Cardioband Mitral/Tricuspid Reconstruction Systems on this potential issue, and on its preventative measures. Important updates to the relevant IFU sections are included in Attachment A and B.

**Customer Instructions:**

- Please review this field safety notice and share information with appropriate clinical staff.
- No patient follow-up or notification is necessary.
- Return completed Acknowledgment form.

Your assistance is appreciated and necessary to ensure this notice is reviewed and understood. This Field Safety Notice has been communicated to the appropriate Regulatory Authorities.

We appreciate your attention and apologize for the inconvenience caused by this matter. If you have questions that have not been answered by this letter, please contact your Edwards Representative at phone: <Local Customer Service>.

Sincerely,

[redacted]

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## ATTACHMENT A – Relevant Mitral IFU Updates

Excerpts from revised Mitral IFU steps are listed below.

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**11.2 Patient Preparation**

6. Place a guidewire in the circumflex artery, if applicable.

**11.6 System Navigation Along the Posterior Annulus**


**Warning**: Avoid damage to adjacent structure during anchor deployment. Throughout the procedure the proximity of the ~~circumflex~~ coronary arter~~y~~ies should be noted. If proximity is uncertain, consider performing coronary angiography. Failure to image the coronary arteries correctly may result in the need for additional medical intervention.

**11.6.1 1st Anchor Placement**

4. Verify tissue contact, the angle between the between the Implant Catheter and the annulus plane, and the distance to the hinge point by using echocardiography under 2D plane view.

5. Prior to first anchor deployment, perform a coronary angiogram to assess location of coronary vessels.


**Warning:** Avoid damage to the adjacent structures during anchor deployment. The proximity of the coronary arteries should be noted in conjunction with intended anchoring location. Failure to image the coronary arteries correctly may result in the need for additional medical intervention.

**11.6.2 Consecutive Anchor Deployment**

5. Verify tissue contact and the angle between the Implant Catheter and the annulus plane, and distance to the hinge point by using 2D & 3D echocardiography.


**Warning:** Avoid damage to the adjacent structures during anchor deployment. The proximity of the coronary arteries should be noted in conjunction with intended anchoring location. Failure to image the coronary arteries correctly may result in the need for additional medical intervention.

**11.10 Size Adjustment Tool Disconnection**

2. ~~Before~~ Prior to disconnection of the Size Adjustment Tool, perform an angiogram to confirm coronary vessel patency. Additionally before disconnection of the Size Adjustment Tool, verify using two planes of fluoroscopy that the Size Adjustment Tool is not pulling the Adjustment Mechanism or the implant.

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## ATTACHMENT B – Relevant Tricuspid IFU Updates

Excerpts from revised Tricuspid IFU steps are listed below.

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### 12.6 System Navigation Along the Posterior Annulus


**Warning**: Avoid damage to the adjacent structure during anchor deployment. Throughout the procedure, the proximity of the ~~right~~ coronary ~~artery~~ arteries should be noted. If proximity is uncertain, consider performing coronary angiography. Failure to image the ~~RCA~~ coronary arteries correctly may result in the need for additional ~~surgical~~ medical intervention.

### 12.6.1 1st Anchor Placement

4. Verify tissue contact, ~~and~~ the angle between the between the Implant Catheter and the annulus plane, and the distance to the hinge point by using fluoroscopy under perpendicular (RAO) view and echocardiography under 2D plane view.

5. Prior to first anchor deployment, perform a coronary angiogram to assess location of coronary vessels.


**Warning:** Avoid damage to the adjacent structures during anchor deployment. The proximity of the coronary arteries should be noted in conjunction with intended anchoring location. Failure to image the coronary arteries correctly may result in the need for additional medical intervention.

### 12.6.2 Consecutive Anchor Deployment

5. Verify tissue contact, ~~and~~ the angle between the Implant Catheter and the annulus plane, and distance to the hinge point by using fluoroscopy under perpendicular (RAO) view and echocardiography under 2D view.


**Warning:** Avoid damage to the adjacent structures during anchor deployment. The proximity of the coronary arteries should be noted in conjunction with intended anchoring location. Failure to image the coronary arteries correctly may result in the need for additional medical intervention.

### 12.10 Size Adjustment Tool Disconnection

3. ~~Before~~ Prior to disconnection of the Size Adjustment Tool, perform an angiogram to confirm coronary vessel patency. Additionally before disconnection of the Size Adjustment Tool, verify using two planes of fluoroscopy that the Size Adjustment Tool is not pulling the Adjustment Mechanism or the implant.

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## (VSU04001 / VSU07001)
## Reference: FCA-151

## CUSTOMER ACKNOWLEDGEMENT

This letter is being returned to confirm that we understand the information provided to us dated <DD MMM YYYY> related to the revised instructions for use listed in the Field Safety Notice. We have shared this information with all appropriate clinical staff at our site. We have also made the information available to personnel that may be using these devices as part of continuing communication and training.

**Hospital / Location:** _____

Hospital Name, City, Country

**Primary Operator:** _____

Print Name

_____

Signature Date

**Please email or fax this Acknowledgement Form to the attention of: Edwards Customer Service,**

<Local EW company name>

<Local EW Company Address>

<Local Customer Service email address>

<Local Customer Service fax number/phone number>