Valtech

A subsidiary of Edwards Lifesciences

URGENT FIELD SAFETY NOTICE

Cardioband Mitral Reconstruction System VSU04001

Reference: FCA-119

<DD MMM YYYY>

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

RE: Cardioband Mitral Reconstruction System IFU

Dear <Physician Names>,

Details on affected devices:

This voluntary notice is being provided to inform you of an important update to the Instructions for Use (IFU) for the Cardioband Mitral Reconstruction System, affecting the following product number: VSU04001 (Cardioband Delivery System).

Description of the problem:

Through an internal review of the Cardioband Mitral Reconstruction System IFU, it was identified that specific instructional steps (including warnings) were mistakenly omitted. The missing steps and warnings provide instructions on deployment of the final two Cardioband anchors, and can be found in Attachment A. While missing from the IFU, the instructions are provided in the physician training deck and each case is supported by an Edwards representative. There have been no reported complaints or adverse events related to this issue, as such it has been determined to have negligible patient safety risk.

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:

While no complaints or patient adverse events have been reported, the following is requested:

- Review this Field Safety Notice
- Return completed Acknowledgement Form

There is no patient follow-up or notification necessary at this time.

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.

Sincerely,

Mark Gayle
Vice President, Quality Assurance
Transcatheter Mitral and Tricuspid Therapies

ATTACHMENT A – Relevant IFU Updates

The missing IFU steps are listed below. For your convenience, the entire IFU section in which these steps occur is listed in Attachment B.

---

13. The red Implant Catheter safety latch will automatically pop up when Implant Catheter scale reaches “2”, indicating the deployment point of the next to last anchor
14. Continue to deploy anchor according to **Steps 1 – 11**.
15. Rotate the knob half a rotation clockwise while pressing the red safety latch of the Implant Catheter. After the half rotation, release the red Implant Catheter safety latch and continue rotating the knob.
16. The Implant Catheter safety latch will pop up once more when reaching number "1", indicating the deployment point of the last anchor.

Warning: When reaching last anchor deployment, make sure the Implant Catheter channel radiopaque marker is distal to implant radiopaque marker. Failure to ensure that the last anchor is deployed in the last segment of the implant may result in anchor detachment.

Warning: Do NOT press the red Implant Catheter safety latch before deployment of the last anchor. This may result in implant disengagement.

17. Continue to deploy anchor according to Steps 1 – 11.

ATTACHMENT B – Full IFU Section including Relevant IFU Updates

The entirety of the 11.6.2, where steps 13-17 (as shown in Attachment A) were missing, is included here for your reference. Missing steps are highlighted with *blue italics*.

11.6.1 Consecutive Anchor Deployment

Note: Manage the Size Adjustment Tool leading wire with minimum slack but no tensioning.

Warning: Three anchors must be deployed before first implant radiopaque marker. Failure to do so may affect the ability to fully contract the implant and/or impact the long-term durability of the implant.

Warning: The imaging views specified during anchor deployment are critical for procedural success (see point 8 below). Failure to follow the imaging requirements may lead to damage to the heart and/or inability to deploy and cinch the implant.

1. Release the implant fabric by turning the Implant Release knob of the Implant Catheter **(Figure 12**) clockwise. When releasing fabric in order to place the 2nd anchor, ensure that the Implant Catheter marker is located within the distal 50-75% of the first segment. When navigating from the 2nd anchor to the 3rd anchor, align the Implant Catheter marker with the first implant radiopaque marker (approximately 2 clicks should be applied). During the remaining anchor placement, align the Implant Catheter marker with the next implant radiopaque marker (approximately 4 clicks should be applied).

Note: To ensure proper anchor placement for the 3rd anchor and subsequent anchors, the Implant Catheter marker should not cross the radiopaque marker on the implant as observed under fluoroscopy.

Note: A scale on the Implant Catheter handle will indicate an estimation of the remaining fabric **(Figure 12)** . The counting scale is an estimate of the number of remaining radiopaque markers and the remaining anchors to be deployed.

Warning: Release of the implant's fabric should always be done under fluoroscopic guidance. Failure to do so may result in implant misplacement and damage to heart structures or an inability to complete the procedure.

2. Navigate the system along the annulus to the next anchoring location by using Left Anterior Oblique fluoroscopy and 3D echo.
3. Insert the Anchor Drive through the Implant Delivery System.
4. Mount the Torque Limiter onto the Anchor Drive.

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

Note: Verify by imaging that the angle between the catheter and implant does not exceed 90°.

6. Rotate the Torque Limiter clockwise under imaging guidance until the anchor is across the Implant Catheter radiopaque marker and has stopped advancing. Fluoroscopy under Right Anterior Oblique view and using 2D (3D for second anchor) echocardiographic views.

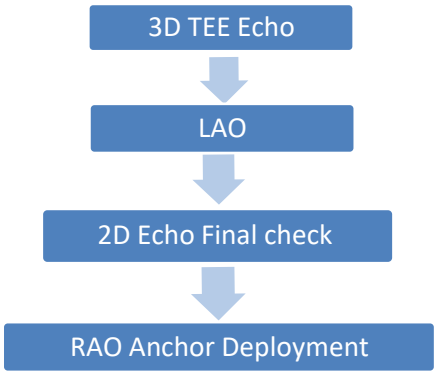
Warning: During anchor deployment, ensure that the Adjustment Mechanism does not move from the lateral towards a medial position as this is an indication of implant rotation. If rotation is observed, anchor deployment should be stopped immediately. Unscrew anchor, reposition and reattempt anchor placement. Failure to do so may result in a damaged cinching wire and lead to an inability to cinch the implant.

Warning: When deploying the 2nd anchor, ensure the angle between the first and second anchor is between 45° and 90° using fluoroscopy. Failure to do so may lead to anchor detachment.

7. Verify the anchor is firmly attached by performing the push-pull test.

Note: Anchor unscrewing for re-positioning can be done at any point before Anchor Drive is released, by rotating the Torque Limiter in the counter-clockwise direction.

8. The imaging sequence below should be followed:



9. Release the anchor by pulling the release levers.
10. Remove the Torque Limiter.
11. Remove the Anchor Drive.

12. For deployment of the consecutive anchors, repeat **Steps 1 – 11**.

13. *The red Implant Catheter safety latch will automatically pop up when Implant Catheter scale reaches "2", indicating the deployment point of the next to last anchor*

14. *Continue to deploy anchor according to **Steps 1 – 11**.*

15. *Rotate the knob half a rotation clockwise while pressing the red safety latch of the Implant Catheter. After the half rotation, release the red Implant Catheter safety latch and continue rotating the knob.*

16. *The Implant Catheter safety latch will pop up once more when reaching number "1", indicating the deployment point of the last anchor.*

***Warning**: When reaching last anchor deployment, make sure the Implant Catheter channel radiopaque marker is distal to implant radiopaque marker. Failure to ensure that the last anchor is deployed in the last segment of the implant may result in anchor detachment.*

***Warning:** Do NOT press the red Implant Catheter safety latch before deployment of the last anchor. This may result in implant disengagement.*

17. *Continue to deploy anchor according to Steps 1 – 11.*

Valtech

A subsidiary of Edwards Lifesciences

<DD MMM YYYY>

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

Acknowledgement Form

Missing Anchor Deployment Instructions for Cardioband Mitral Reconstruction System VSU04001

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 return this signed letter to Edwards Customer Service immediately after review.