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URGENT FIELD SAFETY NOTICE
PRODUCT RECALL – ACTION REQUIRED
Anchor Drive for Cardioband System
Reference: FCA-002

< DD MMM YYYY>

<Physician Name>

<Hospital Name>

<Address>

<City/state/country/zip>

Dear <Physician Name>,

Details on affected devices:

This notice is provided voluntarily to inform you of an urgent product recall on the Anchor Drives used in both the Cardioband Mitral and Tricuspid Reconstruction Systems, product number VSU04002 or VSU05801 (region dependent). We are recalling all lots of this product at this time; a complete list of affected product is attached below.

Description of the problem:

Through the review of recent case reports, we have noted an increased number and rate of Cardioband anchor disengagement events, both during and in the days after mitral implantation. Such anchor disengagements have led, in up to two cases, to Cardioband implant dehiscence requiring intervention. A shift in the Manufacturing process for the anchors, while within our approved specification, is the primary cause of anchor disengagement.

Advice on action to be taken by the user:

Do not use your current inventory of Cardioband Anchor Drives; please return them to Edwards. Your Edwards TMTT Representative will assist with product return, and subsequent product replacement. Only the Anchor Drives are affected by this Field Safety Notice – not the entire Cardioband system.

Many patients treated with the Cardioband to date are in clinical trials; we recommend following-up those patients per their trial protocols. For patients treated outside a clinical study protocol and treated between July and December 2017, we recommend you consider echocardiographic follow-up between 3 – 6 months after implant, or sooner if symptoms warrant.

If there is any finding of concern (i.e. regurgitant jet behind the Cardioband), in Europe please contact Dr. Cyril Moulin (phone: +41 22 787 4351 or Cyril.Moulin@edwards.com), in the US please contact Dr. Thomas Morrissey (phone: +1-949-250-2042 or Thomas.Morrissey@edwards.com) at Edwards Lifesciences in order to report the event and discuss potential treatment paths. Edwards is dedicated to partnership with you and your patients on any such matter.

There is no risk of anchor embolization after disengagement; the anchors remain securely attached inside the Cardioband implant.



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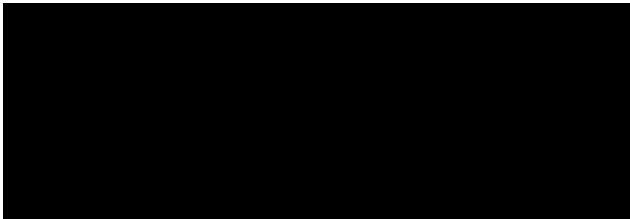
Customer Instructions:

- Review this field safety notice to understand the potential hazard and share information with appropriate clinical staff at your site.
- Complete the attached Acknowledgement Form, and return it to your Edwards TMTT Representative.
- Work with your Edwards TMTT Representative to return any impacted product (see attached list below).
- For patients treated between July and December 2017, consider echocardiographic follow-up at 3 – 6 months after implantation, or sooner if symptoms warrant.

Your assistance is necessary to ensure that 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 impact of this matter. If you have questions that have not been answered by this letter, please contact your Edwards TMTT Representative.

Sincerely,





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List of Affected Serial Numbers:

| Model Number: VSU04002 |
|---|
| 170503/1, 170503/2, 170503/3, 170503/4, 170503/5, 170503/6, 170503/7, 170503/8, 170503/9, 170503/10, 170503/11, 170503/12, 170503/13, 170503/14, 170503/15, 170503/16, 170503/17, 170503/18, 170503/19, 170503/20, 170503/21, 170503/22, 170503/23, 170517/1, 170517/2, 170517/3, 170517/4, 170517/5, 170517/6, 170521/1, 170521/2, 170521/3, 170521/4, 170521/5, 170521/6, 170521/7, 170521/8, 170522/1, 170522/2, 170539/1, 170539/2, 170539/3, 170539/4, 170539/5, 170539/6, 170539/7, 170539/8, 170539/9, 170539/10, 170539/11, 170549/1, 170549/2, 170549/3, 170549/4, 170549/5, 170549/6, 170549/7, 170550/1, 170550/2, 170550/3, 170550/4, 170551/1, 170551/2, 170551/3, 170551/4, 170551/5, 170551/6, 170552/1, 170552/2, 170552/3, 170552/4, 170552/5, 170552/6, 170552/7, 170552/8, 170552/9, 170552/10, 170552/11, 170552/12, 170552/13, 170614/1, 170614/2, 170614/3, 170615/1, 170615/2, 170615/3, 170615/4, 170615/5, 170615/6, 170615/7, 170615/8, 170615/9, 170615/10, 170615/11, 170615/12, 170615/13, 170615/14, 170615/15, 170615/16, 170615/17, 170618/1, 170618/2, 170618/3, 170618/4, 170618/5, 170619/1, 170619/2, 170619/3, 170619/4, 170619/5, 170619/6, 170619/7, 170619/8, 170643/1, 170643/2, 170643/3, 170643/4, 170643/5, 170643/6, 170643/7, 170643/8, 170644/1, 170644/2, 170644/3, 170644/4, 170644/5, 170644/6, 170644/7, 170644/8, 170644/9, 170644/10, 170645/1, 170645/2, 170645/3, 170645/4, 170645/5, 170645/6, 170645/7, 170645/8, 170645/9, 170645/10, 170645/11, 170645/12, 170650/1, 170650/2, 170650/3, 170650/4, 170650/5, 170650/6, 170650/7, 170650/8, 170650/9, 170650/10, 170650/11, 170650/12, S20000, S20001, S20002, S20003, S20004, S20005, S20006, S20007, S200000, S200001, S200002, S200003, S200004, S200010, S200011, S200012, S200013, S200014, S200015, S200016, S200017, S200018, S200019, S200020, S200021, S200022, S200023, S200024, S200025, S200026, S200027, S200028, S200029, S200030, S200038, S200039, S200040, S200041, S200042, S200043, S200044, S200045, S200056, S200057, S200058, S200059, S200060, S200061, S200062, S200063, S200064, S200065, S200066, S200067, S200068, S200069, S200070, S200071, S200072, S200073, S200074, S200075, S200076, S200077, S200136, S200137, S200138, S200139, S200140, S200141, S200142, S200143, S200144, S200145, S200146, S200147, S200148, S200149, S200150, S200151, S200152, S200153, S200154, S200155, S200156, S200157, S200158, S200159, S200160, S200161, S200162, S200278, S200279, S200280, S200281, S200282, S200283, S200284, S200285, S200286, S200287, S200288, S200289, S200290, S200291, S200292, S200293, S200296, S200297, S200298, S200299, S200300, S200301, S200313, S200314, S200315, S200316, S200317, S200318, S200319, S200320, S200396, S200397, S200398, S200399, S200400, S200401, S200402, S200403, S200404, S200405, S200406, S200407, S200408, 200409, S200410, S200411, S200412, S200413, S200414, S200415, S200416, S200420, S200421, S200422, S200423, S200424, S200425, S200426, S200427, S200428, S200429, S200430, S200431, S200432, S200433, S200434, S200435, S200436, S200437, S200438, S200439, S200461, S200519, S200520, S200521, S200522, S200523, S200827, S200828, S200829, S200830, S200831, S200832, S200833, S200834, S200835, S200836, S200837, S200838, S200839, S200840, S200884, S200885, S200886, S200887, S200888, S200889, S200890, S200891, S200892, S200893, S200894, S200895, S200896, S200897, S200898, S200899, S200900, S200901, S200902, S200903, S200904, S200905, S200906, S200907, S200908, S200909, S200910, S200921, S200922, S200923, S200924, S200925, S200926, S200927, S200928, S200929, S200930, S200931, S200932, S200933, S200934, S200935, S200936, S200937, S200938, S200939, S200940, S200941, S200942, S200943, S200944, S200945, S200946, S200947, S200948, S200949, S200950, S200951, S200952, S200953, S200954, S200955, S200956, S200978, S200979, S200980, S200981, S200982, S200983, S200994, S200995, S200996, S200997, S200998, S200999, S201000, S201001, S201002, S201003, S201004, S201005, S201006, S201007, S201008, S201009, S201010, S201011, S201012, S201013, S201014, S201015, S201016, S201017, S201018, S201019, S201020, S201021, S201022, S201023, S201024, S201025, S201026, S201354, S201355, S201356, S201357, S201389, S201390, S201391, S201392, S201393, S201394, S201395, S201396, S201397, S201398, S201403, S201404, S201405, S201406, S201407, S201408, S201409, S201410, S201411, S201412, S201413, S201414, S201415, S201416, S201417, S201418, S201419, S201420, S201428, S201429, S201430, S201465, S201466, S201467, S201468, S201469, S201470, S201471, S201472 |

| Model Number: VSU05801 (US only) |
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| 170579/1, 170579/2, 170579/3, 170579/4, 170579/5, 170579/6, 170579/7, 170579/8, 170579/9, 170579/10, 170579/11, 170579/12, 170579/13, 170579/14, 170579/15, 170579/16, 170579/17, 170579/18, 170579/19, 170579/20, 170579/21, S200236, S200237, S200238, S200239, S200240, S200241, S200242, S200243, S200244, S200245, S200246, S200247, S200248, S200249, S200250, S200251, S200252, S200253, S200254, S200255, S200256, S200257, S200258, S200259, S200260, S200261, S200262, S200263, S200264, S200265 |



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**URGENT FIELD SAFETY NOTICE
PRODUCT RECALL – ACTION REQUIRED
Anchor Drive for Cardioband System
Reference: FCA-002**

< DD MMM YYYY>

<Hospital Name>

<Address>

<City/state/country/zip>

Acknowledgement form

This letter is being returned to confirm that we understand the information provided to us dated <DD MMM YYYY> related to the field safety notification of Cardioband Anchor Drives. We have shared this information with all appropriate clinical staff at our site.

Hospital / Location: <Name, City, Country> _____

Primary Operator: <Name> _____

Primary Operator Signature: _____ Date: _____

Please return this signed letter to your Edwards TMTT Representative immediately.

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Recall Inventory Form

Note: Please indicate "NONE" in the column "Number of Units to be Returned" if you do not have any inventory to return.

| Model Number | Lot Number | Qty Shipped from Edwards | Number of Units used | Number of Units to be Returned |
|--------------|------------|--------------------------|----------------------|--------------------------------|
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RGA Number: _____