



## **URGENT FIELD SAFETY NOTICE**

**Edwards Lifesciences IntraClude™ Intra-aortic Occlusion Device (ICF100)**  
**Reference: FCA-125**

### **Possible Inter-Lumen Leak – Action required**

[DATE OF LETTER]

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

Attention: Risk Management Department  
cc: Chief of Cardiac Surgery, Director of Operating Room Services

RE: Edwards Lifesciences IntraClude™ Intra-aortic Occlusion Device Model ICF100

Dear Valued Customer,

Edwards Lifesciences would like to advise you of action to be taken by users of IntraClude™ intra-aortic occlusion device Model ICF100, used in cardiopulmonary bypass surgery.

Edwards Lifesciences has identified a potential safety risk which may occur during the use of the IntraClude intra-aortic occlusion device (ICF100). Edwards Lifesciences has received a limited number of customer reports regarding an inter-lumen leak between the cardioplegia lumen and pressure lumen in the device.

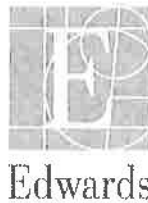
If present, the leak will be detected after the device is advanced into the ascending aorta, but before the balloon is inflated. The detection will occur when, as stated in the Instructions for Use, the aortic root vent is turned on, which is the last step prior to inflating the balloon. When present, the leak will result in aortic root pressure dropping to 0 mmHg or less due to the vacuum being pulled on the aortic root vent line.

#### **Potential Hazard**

If the leak exists, consistent delivery of cardioplegia may not be possible. Presence of this leak may require the medical staff to replace the device with another IntraClude, apply a cross-clamp during the procedure, or utilize an alternative method for cardioplegia delivery. No reports of illness or injury have been reported in any of the complaints relating to this issue.

#### **Affected Product**

All lot numbers of Edwards Lifesciences IntraClude™ intra-aortic occlusion device (ICF100).



### **Customer Instructions**

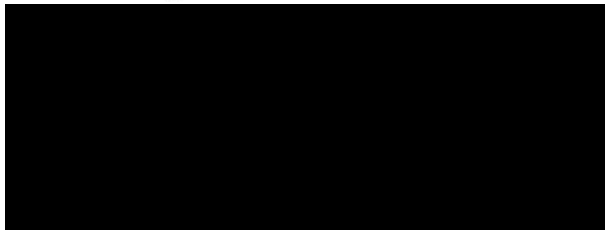
1. Review this field safety notice to understand the potential hazard.
2. Meet and review with appropriate clinical staff at your institution.
3. Complete and return the acknowledgement form attached to this letter via fax to [insert local Customer Service fax number] or email to [insert local Customer Service email] within five (5) business days of receiving this notice.
4. Distribute this notice within your organization or to any organization where the potentially affected devices may have been transferred.
5. Product may continue to be used. Product return is not required.

Your assistance is appreciated and necessary to ensure that this notice is reviewed and acknowledged.

Edwards has communicated this Field Safety Notice to 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 call Edwards Customer Service Monday through Friday at [insert local Customer Service telephone number] from [insert local Customer Service operating hours].

Sincerely,



Edwards Lifesciences



Edwards

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**Reference: FCA-125**

**Acknowledgement Form**

[DATE OF LETTER]

**Reason for action: Potential inter-lumen leak between the cardioplegia lumen and pressure lumen in all lots of the IntraClude™ intra-aortic occlusion device (ICF100)**

This acknowledgement form confirms that we understand the information in the Urgent Field Safety Notice dated [DATE OF LETTER]. 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

[insert local EW company name]

[insert local EW company address]

[insert local Customer Service email address]

[insert local Customer Service fax number]