FSN Ref: FCA-134 FSCA Ref: FCA-134

Date: 30/05/2019

Urgent Field Safety Notice
Edwards Lifesciences IntraClude™ Intra-aortic Occlusion Device (Model ICF100)

For Attention of*:To: <<Customer Name>> <<Customer Address>> <<Customer City, State, Postal Code>> <<Customer Country>>

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

Company Name/Logo

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Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	The IntraClude Intra-Aortic Occlusion Device (model number ICF100) is a triple-lumen catheter with an elastomeric balloon near its distal tip designed to occlude the ascending aorta in order to partition the aortic root from arterial circulation. The balloon expands to occlude a range of aorta sizes from 20 to 40 mm. This device is designed to be used in the femoral approach with the Edwards EndoReturn (ER21B or ER23B) arterial cannula or the Edwards Introducer Sheath (IS19A). The shaft is provided with an extended strain relief, which tapers from 10.5 Fr to the remaining 9 Fr catheter, and is designed to prevent kinking at the hub and to avoid compressing the shaft when the hemostasis valve of the Edwards EndoReturn (ER21B or ER23B) arterial cannula or Edwards Introducer Sheath (IS19A) is firmly closed. The large central lumen of the IntraClude Device serves three functions: accommodating the guidewire, delivering cardioplegia solution to the aortic root, and venting fluid and air from the aortic root. The two remaining lumens serve as conduits for balloon inflation/deflation and aortic root pressure monitoring. The hub has two flexible extension tubes with an integrated luer connection to provide access for the accessories. The shaft is provided with markers to indicate the insertion depth. A blue Clamp-Lock device, provided on the extended strain relief portion, allows the IntraClude Device to be locked in position.The IntraClude Intra-Aortic Occlusion Device is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude Intra-Aortic Occlusion Device occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.
1.	2. Commercial name(s)
	IntraClude Intra-Aortic Occlusion Device
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	The IntraClude intra-aortic occlusion device is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude intra-aortic occlusion device occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.
1.	5. Device Model/Catalogue/part number(s)*
	ICF100
1.	6. Software version
	N/A

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1.	7. Affected serial or lot number range
	Only lot numbers 60972890 61078031 61097633 61139239 61259627 61259628 61713218 61723505 61898939
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	If the IntraClude balloon bursts during cardiopulmonary bypass, the heart can fill and warm, the operative site may be obscured, and the device will need to be exchanged or operative strategy would need to change, including placement of an external cross-clamp, conversion to an open procedure, or performing the procedure under fibrillation. It is possible for an injury to occur as a result of a balloon burst that leads to a change in operative strategy.
2.	2. Hazard giving rise to the FSCA*
	The issue involves balloon bursts during IntraClude use. The IntraClude device is essential to occlude the aorta and provide the necessary cardiac isolation required to perform minimally invasive cardiac surgery procedures. If the IntraClude balloon bursts during cardiopulmonary bypass, the heart can fill and warm, the operative site may be obscured, and the device will need to be exchanged or operative strategy would need to change, including placement of an external cross-clamp, conversion to an open procedure, or performing the procedure under fibrillation
2.	3. Probability of problem arising
	Harm may occasionally occur
2.	4. Predicted risk to patient/users
	The risk is considered as High
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Edwards received some complaints regarding Edwards IntraClude Intra-Aortic Occlusion Device (Model ICF100) related to balloon rupture/puncture, the complaint rate is within the expected occurrence rate, however there were an increase of the number of complaints received between January and April 2019. The issue involves balloon bursts during IntraClude use
2.	7. Other information relevant to FSCA
	N/A

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	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Review this field safety notice to understand the potential hazard Complete and return the Customer Reply Form Distribute this notice within your organization or to any organization where the potentially affected devices have been transferred. If you have further distributed this product, notify your customers to the user level. Report any balloon failures to Edwards Lifesciences.	
3.	2. By when should the action be completed?	Within five (5) business days of receiving this notice to Customer Service
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Section not applicable	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None N/A	
3	6. By when should the action be completed?	By 31-July -2019
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

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	Choose an item.	Choose an item.

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Edwards Lifesciences LLC
	b. Address	One Edwards Way Irvine, CA 92614
	c. Website address	www.edwards.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Customer Reply Form
4.	10. Name/Signature	Frédérique Pedretti Vice President, Quality Edwards Lifescience

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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	Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	Pre-filled by manufacturer
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	Pre-filled by manufacturer
Product Code(s)	1 2 3
Batch/Serial Number (s)	1 2 3

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	

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☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

4. Return acknowledgement to sender	
Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.