

Edwards Lifesciences Recalls the IntraClude Intra-Aortic Occlusion Device Due to Risk of Balloon Rupture

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- IntraClude Intra-Aortic Occlusion Device ICF100
Model: ICF100
UDI code (01) 00690103190007
Lots:
60972890 61078031 61097633 61139239 61259627
61259628 61713218 61723505 61898939
- Distribution Dates: May 1, 2017 to February 19, 2019
- Devices Recalled in the U.S.: 757
- Date Initiated by Firm: May 14, 2019

Device Use

The IntraClude Intra-Aortic Occlusion device is used in patients undergoing cardiopulmonary bypass - a technique in which a machine temporarily takes over the function of the heart and lungs during surgery.

When the IntraClude balloon is inflated, the device blocks and vents (occludes) the aorta so that the heart is assessed without interference of other organs.

Reason for Recall

Edwards LifeSciences is recalling the IntraClude Intra-Aortic Occlusion Device due to a risk of balloon rupture during use, which may add time to the procedure and compromises the safety of the patient.

The IntraClude balloon bursting may cause serious adverse health consequences related to increased time the patient is on cardiopulmonary bypass, including neurological damage, embolism, stroke and death.

The firm has received 22 complaints related to balloon rupture or puncture. Three deaths have been reported.

Who May be Affected

- Patients who undergo procedures involving the IntraClude Intra-Aortic Occlusion Device.
- Health care providers, distributors and facilities using IntraClude Intra-Aortic Occlusion Device.

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What to Do

On May 14, 2019, Edwards Lifesciences issued an Urgent Recall Notification sent to customers, listing the following actions:

Customers

- Review the field safety notice to understand the potential hazard.
- Complete and return the attached Acknowledgement Form within five business days of receiving this notice to Customer Service via fax at (800) 422-9329 or email to cs.usfaxes@edwards.com (<mailto:cs.usfaxes@edwards.com>)
- Complete and return the Product Reconciliation Form to Customer Service:
 - Record the quantity of any of the listed lot numbers in your possession
 - Contact Customer Service to arrange return and replacement of affected devices, and
 - Return affected devices to Edwards with the Return Goods Authorization (RGA) provided.
- 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.
- Your assistance is appreciated and necessary to ensure that this notice is reviewed, and that the response forms and affected devices are returned promptly.

Contact Information

For questions or concerns regarding this notification, please call Edwards Customer Service Monday through Friday at (800) 424-3278, Option 1, from 8:00 AM – 4:00 PM Pacific Time.

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX.

More Information

FDA Medical Recall Database Class 1 Recall ntraClude IntraAortic Occlusion Device (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=172949>)