

**[High Priority ] - A32712 : Edwards—IntraClude Intra-Aortic Occlusion Devices: Balloon Rupture May Occur  
Medical Device Ongoing Action**

**Published:** Friday, May 17, 2019

**UMDNS Terms:**

- Occluders, Vascular [17731]
- Cannulae, Arterial [10564]

**Product Identifier:**

[Consumable]

Product	Edwards Lifesciences Corp Model	Lot No.	UDI
IntraClude Intra-Aortic Occlusion Devices	ICF100	60972890, 61078031, 61097633, 61139239, 61269627, 61269628, 61713218, 61723605, 61898939	(01) 00690103190007

**Geographic Regions:** Australia, Austria, Belgium, Canada, Colombia, Czech Republic, France, Germany, Italy, The Netherlands, Poland, Romania, Sweden, Switzerland, United Arab Emirates, U.K., U.S.

**Manufacturer(s):** Edwards Lifesciences Corp1 Edwards Way, Irvine, CA 92614, United States

**Suggested Distribution:** Cardiology/Cardiac Catheterization Laboratory, Critical Care, OR/Surgery, Materials Management

**Problem:**

In a May 14, 2019, Urgent Product Recall letter submitted by an ECRI Institute member hospital, Edwards states that balloon rupture may occur during use of the above devices. Edwards also states that 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 the operative strategy will 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 because of a balloon burst that leads to a change in operative strategy.

**Action Needed:**

Identify any affected product in your inventory. If you have affected product, verify that you have received the May 14, 2019, Urgent Product Recall letter, Acknowledgment Form, and Product Reconciliation Form from Edwards. Complete the Acknowledgment Form and the Product Reconciliation Form, and return them to Edwards using the instructions on the forms. To arrange for product return and replacement, contact the Edwards customer service department using the information below. Return affect product to Edwards using the provided return goods authorization (RGA). Notify all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed affected product. Report any balloon failures to Edwards.

**For Further Information:**

Edwards customer service department  
Tel.: (800) 424-3278 (select option 1), 8 a.m. to 4 p.m. Pacific Time  
Website: [Click here](#)

**Comments:**

- This alert is a living document and may be updated when ECRI Institute receives additional information.

**Source(s):**

- 2019 May 16. Member Hospital. Ref: #FCA-134 (includes reply form) [Download](#)
- 2019 May 17. Manufacturer. The manufacturer confirmed the information provided in the source material.