Edwards Lifesciences
URGENT: PRODUCT RECALL
ACTION REQUIRED
Field Corrective Action # 192
Product: OptiSite Arterial Cannula & Femoral Arterial Cannula

Model Numbers: OPTI16, OPTI18, FEMII016A, FEMII016AS, FEMII018A and FEMII018AS
See Table 1 for model and UDI
Lot Numbers: See Customer Acknowledgement Form

13 MAY 2025

«**Ship to Number**»
Attention: Risk Management and Department of Cardiac Surgery
«Ship to Description»
«Ship to Addr Line 1»
«Ship to City», «Ship to State» «Ship to Zip»

Dear Valued Customers and Distributors:
Edwards Lifesciences is voluntarily notifying customers of an issue regarding certain lots of certain sizes of OptiSite Arterial Perfusion and Femoral Arterial Cannula.

Intended Use:
Edwards Lifesciences arterial perfusion cannula are indicated for arterial perfusion in the extracorporeal circuit for < 6 hours.

Edwards Lifesciences Femoral Access Cannulae are intended for use in situations which require rapid femoral venous and arterial access for short-term (≤ 6 hours) cardiopulmonary bypass. Vessel access (venous or arterial) is left to the discretion of the physician.

Description of the Problem:
Edwards has confirmed a small number of occurrences impacting the OptiSite Arterial Perfusion cannula in which a 3mm to 4mm section of wire, from the wire-reinforcement coil at the cannula tip, was found to be released from the cannula body.

As certain Femoral Arterial Cannula models are made of the same components as the impacted OptiSite Arterial Perfusion cannula, the scope of this notice includes these Femoral Arterial Cannula models.

Risk to Health:
The released wire at the tip of the cannula was identified prior to any procedures being performed. The complaints have not resulted in any injury. The risk for the wire-reinforcement coil protruding out of the cannula body is major tissue damage and hemolysis.

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Actions to be Taken:

Review this letter for awareness and advice on action to be taken.

Do not use your current inventory of affected units as identified by serial numbers in the attached acknowledgement form. Your Edwards enableCV (eCV) Representative will assist with product return.

Only specifically identified UDI numbers are affected by this product recall – no other OptiSite Arterial Cannula or Femoral Arterial Cannula are impacted.

Customer and Distributor Instructions:

Please ensure the following:

- Verify your inventory on the attached customer acknowledgement form.
- Share this notice with appropriate clinical staff at your site.
- No patient follow-up or notification is necessary.
- Return a completed **Customer Acknowledgment Form** to your Edwards eCV Representative or via email to Edwards Customer Service at FCA_ECV@edwards.com within 15 days of receipt of this notification.
- After receiving RGA number, return any impacted product to Edwards at the address below. A credit will be issued upon receipt of returned product.

enableCV Distribution Center
6644 W. 2100 S. Suite D
West Valley, UT 84128

Distributors: Please notify your customers by sending this customer notification to all of your customers who have purchased the impacted Edwards product.

Your assistance is necessary to ensure that this notice is reviewed and understood. This Field Corrective Action is being communicated by Edwards to the applicable 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 eCV Representative.

Sincerely,

Dannette Crooms
Vice President of Quality & Regulatory, eCV

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Table 1

Product Family	Model Number	UDI
OptiSite Arterial Perfusion Cannulae	OPTI16	00690103180558
	OPTI18	00690103180565
Peripheral Femoral Arterial Cannula	FEMII016A	00690103031232
	FEMII016AS	00690103168341
	FEMII018A	00690103031256
	FEMII018AS	00690103168358

Adverse Event Reporting in the US:
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form or submit by fax to 1-800-FDA-0178.

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CUSTOMER ACKNOWLEDGEMENT FORM

«Ship to Number»
Attention: Risk Management and Department of Cardiac Surgery
«Ship to Description»
«Ship to Addr Line 1»
«Ship to City», «Ship to State» «Ship to »

Dear Customers and Distributors:

Please review and verify your inventory in the table below for your impacted devices.

- Share this notice with the appropriate clinical staff at your site.
- No patient follow-up or notification is necessary.
- Complete ALL sections of the table below, indicate the number of units used and the number of units to be returned.
- Return a completed **Customer Acknowledgment Form** to your Edwards eCV Representative or via email to Edwards Customer Service at FCA_ECV@edwards.com within 15 days of receipt of this notification.
- Call Customer Service at 1-888-943-2783, or email: FCA_ECV@edwards.com to obtain a Returned Goods Authorization (RGA) number and record your RGA number(s) below.
- After receiving RGA number, return any impacted product to Edwards at the address below. A credit will be issued upon receipt of returned product.

  EnableCV Distribution Center
  6644 W. 2100 S. Suite D
  West Valley, UT 84128

- Distributors: Please notify your customers by sending this customer notification to any of your customers who have purchased the impacted Edwards product.

  Contact Edwards Customer Service at **FCA_ECV@edwards.com** or your Edwards eCV Representative with questions.

RGA number(s): _____

Model	Lot Number	Quantity Received	Quantity Used	Quantity to be Returned
<ITEM>	<LOT_NBR>	<QTY_SHIPPED>		

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CUSTOMER ACKNOWLEDGEMENT FORM

- Customers/Distributors: In the below table, please document any impacted inventory not identified above. If not applicable, leave this table blank.

Model	Lot Number	Quantity Received	Quantity Used	Quantity to be Returned

Name (Print):	
Title/Dept.	
Telephone Number:	
E-mail:	
Signature / Date:	