URGENT PRODUCT RECALL – ACTION REQUIRED
FCA #122
Swan Ganz Thermodilution Catheter
Model Numbers: 131F7, 131F7P, 131VF7P, 151F7

Lot Numbers: 61176373, 61321254, 61176369, 61176314, 61176370, 61176367, 61176374, 61321241, 61311580

<MM DD, YYYY>

<Customer #>
<Contact name or Dept.>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Dear Valued Customer:

As part of our strong commitment to quality, we continuously monitor our products throughout their life cycle to quickly identify and correct any potential issues. We recently discovered an issue with specific Swan-Ganz catheters and are initiating a voluntary recall and notifying applicable Regulatory Authorities.

We request that you return any unused units that are currently in your inventory with the model and lot numbers referenced above. Once returned, replacement product will be shipped to you at no charge. For your convenience, we have prepopulated the attached acknowledgement form with the affected lots you have received. Please follow the instructions in the acknowledgement form to complete the recall process.

Description of product being recalled:
The Swan-Ganz Thermodilution Catheter provides a diagnostic tool for physicians to rapidly determine hemodynamic pressures and cardiac output when used with a compatible cardiac output computer.
Swan-Ganz Thermodilution Catheters are indicated for the assessment of a patient's hemodynamic condition through direct intra-cardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions.

The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.

Description of the problem:
This non-conformance involves Swan Ganz catheters with incorrect lumen assembly, which causes reversal of the lumens. If the lumens are reversed the clinician may note reverse PA and CVP pressure values and waveforms. It is possible for unintended treatment due to inaccurate values if the reversal in waveforms is not noticed. We believe only a small amount of units within the lots identified are impacted.

There were no patient complications reported.

At Edwards Lifesciences, we are committed to helping you advance the care and treatment of patients. This commitment extends to the products, service, education, and support we provide. We apologize for any inconvenience caused by this action and appreciate your attention in this matter.

If you have any questions, please contact **Edwards Customer Service at +971 4 299 1025**.

Sincerely,

Michael Collins
Vice President of Quality, Critical Care

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CUSTOMER ACKNOWLEDGEMENT

<Customer #>
<Firm Name>
<Attention: RISK MANAGEMENT>
<Address>
<City/state/zip>

Please follow all instructions below to complete the recall process.

Complete this acknowledgement form with the following information:

- Verify your inventory
- Complete all sections of the table below, indicate “0” if you have no product to return
- If you have unused product to return, call Customer Service at the number below to obtain a Returned Good Authorization (RGA) number.
- Fax the completed form to Edwards Customer Service at +971 4 299 1025, within 10 days from receipt of this notification

Model	Lot Number	Quantity Shipped From EW	Number of units to be returned	RGA Number

Name (Print): _____

Telephone Number: _____

Signature: _____

Date: _____