URGENT FIELD SAFETY NOTICE

FCA #130

Swan-Ganz Thermodilution Catheter Double Lumen (model 110F5)

Lot Numbers: 59618641, 61288962, 61369065, 61427662, 61442146, 61478805, 61516527, 61516529, 61553510, 61553511, 61561846, 61583541, 61570128, 61689706, 61697951, 61707672 and 61719708.

<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 became aware of an issue with Edwards Swan Ganz Catheter model 110F5 and are notifying our customers. This is a voluntary notification and the appropriate Regulatory Authorities have been notified. We are not recalling any product.

Details on affected devices:

The family of Swan-Ganz flow-directed monitoring catheters provides a rapid, simple, and effective method for monitoring right heart pressures, sampling mixed venous blood, and infusing solutions.

Monitoring catheters are available in both double and triple lumen models. In double lumen catheters, the larger lumen terminates at the distal tip of the catheter and is used to monitor pulmonary artery and wedge pressures; the distal lumen may also be used for sampling of mixed venous blood and infusing solutions. The smaller lumen permits balloon inflation and deflation. Triple lumen monitoring catheters with the additional (proximal) lumen for central venous pressure monitoring.

Description of the problem:

This non-conformance involves a Swan Ganz catheter with incorrect printing on the hub of the catheter in reference to balloon inflation volume. The catheter has 0.5 mL printed on the catheter hub, but the IFU calls for 0.8mL to fill the balloon, which is the correct inflation volume**.** Under-inflation of the balloon may cause an inability to appropriately float the catheter to wedge position

Edwards Lifesciences AG
Branch Amazon Court, Karolínská 661/4,186 00 Prague 8, Czech Republic
Phone: +420 221 703 404 Fax:+420 222 315 611
Email: customer_service_EEMEA@edwads.com

and may make it difficult to obtain a wedge pressure. This may cause the device to be removed and re-inserted causing a procedural delay. Refer to IFU for correct inflation volume.

Description and indication of product:

Swan-Ganz flow-directed monitoring catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

If you have any questions, please contact **Edwards Customer Service or Tech Support at tel.: 0870 606 2040.**

Sincerely,

Michael Collins
Vice President of Quality, Critical Care

This Urgent Field Safety Notice has been communicated by Edwards Lifesciences to the relevant competent authority

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CUSTOMER ACKNOWLEDGEMENT

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

Please follow all instructions below to complete the acknowledgement process.

Complete this acknowledgement form with the following information:

- DO NOT return any product
- Verify your inventory
- Refer to IFU for correct inflation parameters as 0.8mL
- Complete all sections of the table below, indicate “0” if you have no product
- Email the completed form to Edwards Customer Service on UK_CustomerService@Edwards.com within 10 days from receipt of this notification

Model	Lot Number	PO#	Ship To Date	Quantity Shipped From EW	Number of units in inventory

Name (Print): _____

Title/Dept. _____

Telephone Number: _____

Signature: _____

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Edwards

Date: _____

Please return this form via fax to Edwards Customer Service or Tech Support at tel.: 0870 606 2040, email: UK_CustomerService@Edwards.com**.**

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