URGENT FIELD SAFETY NOTICE

FCA # 165

Product: PediaSat Catheter
Model Numbers: XT3515SP and XT358SP

Lot Numbers: See table in Acknowledgement Form.
UDI Codes: 00690103197532 and 00690103197525

ACTION REQUIRED

July 9, 2021

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

Dear Valued Customers and Distributors:

Edwards Lifesciences is voluntarily notifying customers of a product correction related to interlumen leaks in PediaSat Catheters with the model numbers listed above. There is no need to return product at this time.

Details on affected devices:

PediaSat catheters are indicated for hemodynamic monitoring through blood sampling, pressure monitoring, and oxygen saturation measurements in adults and/or pediatric patients.

The PediaSat oximetry catheters are non-balloon catheters that provide the means for infusion of solutions, measuring pressure, and taking blood samples. These catheters also provide the means for continuously monitoring oxygen saturation.

Description of the problem and indication to the user and distributor:

Edwards has received three (3) customer complaints reporting leaks during use. One complaint noted that after administering medication, the physician flushed a different lumen than the one where the medication was administered, and the patient's vital signs responded to the medication. The other two complaints noted external leakage at the transition from the green hub to the tube. Edwards has confirmed a manufacturing defect leading to possible interlumen leakage.

Risk to health is limited as the volume of the catheter is 0.3cc and that is the maximum volume of medication that can be additionally delivered to the patient. You may observe a transient change in vital signs from the micro dose of medication. You may experience a minimal delay in your procedure during the time the product is being removed and exchanged if a leak occurs.

The problem may be identified during preparation of the catheter for insertion per the IFU, paying specific attention to the connection between the green hub and the tubing for any signs of leakage. Additionally, the problem may be identified if when flushing the lumens of the catheter while administering a medication, a transient change of vital signs is observed.

In either of these situations, remove the catheter over a guidewire maintaining venous access and then place a new product over the venous wire. Once properly placed, remove the guidewire, and secure the catheter. New venous access is not required.

Please follow the instructions included in the enclosed acknowledgement form and listed below. Return the acknowledgement form to XXXX@edwards.com.

- There is no need to return product at this time.
- Distribute this notice within your organization or to any organization where the potentially affected devices have been transferred.
- E-mail the completed form to Edwards Customer Service at XXXX@edwards.com within 5 days from receipt of this notification.

Product can be used as indicated above.

Please provide this notification to all individuals within your organization who need to be made aware. Please transfer this notice to other organizations if the impacted product has been transferred or distributed.

Your assistance is appreciated and necessary to ensure that this notice is reviewed and understood. This Field Corrective Action has been communicated by Edwards to the applicable Competent Authorities.

If you have any questions, please contact Edwards Customer Service at XXX-XXX-XXX.

Sincerely,

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Vice President of Quality, Critical Care

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ACKNOWLEDGEMENT FORM

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

Distributors:
Please complete the acknowledgement form and forward the Customer Letter to any of your customers who have purchased the impacted Edwards PediaSat Catheters noted in the table below and ask them to return this acknowledgement form.

Customers and Distributors:

- No product needs to be returned.
- Distribute this notice within your organization or to any organization where the potentially affected devices have been transferred.
- E-mail the completed form to Edwards Customer Service at XXX@edwards.com within 5 days from receipt of this notification.
- Product can be used as indicated in the Customer Letter. If you have any questions, you may call Customer Service at XXX-XXX-XXX.

Model	Lot Number	PO#	Quantity Shipped From EW	Unit of Measure
				EA

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