URGENT FIELD SAFETY NOTICE
PRODUCT RECALL - ACTION REQUIRED
FCA # 179

Products: PASCAL Precision Transcatheter Valve Repair System
Model Number(s): 20000ISM and 20000IS
Serial Number(s): See Table in Acknowledgement Form
Basic-UDI Code: 0690103S004PAS000BC

<MM DD, YYYY>

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

<Attention: RISK MANAGEMENT>

RE: Implant System for Edwards PASCAL Precision Transcatheter Valve Repair System

Dear Valued Customer and Distributors,

Edwards Lifesciences (SRN: US-MF-000007139) is voluntarily notifying customers of a product recall of specific serial numbers of the PASCAL Precision product that may be impacted by a manufacturing process that could result in the product not operating as intended.

Details on affected devices:

The PASCAL Precision system is intended to repair an insufficient mitral and/or tricuspid valve via percutaneous reconstruction through tissue approximation. The PASCAL Precision system percutaneously delivers the implant to the valve via a femoral vein access using a transvenous, transseptal (mitral) and transvenous (tricuspid) approach.

The Implant System for Edwards PASCAL Precision Transcatheter Valve Repair System consists of the steerable catheter (outermost layer), the implant catheter (innermost layer), and the implant (hereinafter refers to the PASCAL and PASCAL Ace implants).

Description of the problem:

Based on information obtained through post-market surveillance, some physicians have experienced resistance when attempting to release the implant from the delivery system by rotating the release knob. This created a situation where additional torque was required to initiate rotation of the release wire from the implant and in some cases implant rotation was observed on fluoroscopy. All reported

cases ultimately resulted in successful implant release, however one case reported potential impact to Mitral Regurgitation (MR) resolution, which was addressed with a second PASCAL implant.

Action to be taken by the user:

Do not use your current inventory of affected units as identified by serial numbers in the attached acknowledgment form.

Your Edwards TMTT Representative will assist with product return and subsequent product replacement.

Only specifically identified serial numbers are affected by this product recall – no other PASCAL Transcatheter Valve Repair Systems are impacted.

Customer and Distributor Instructions:

Our records indicate that impacted product, as identified by their serial numbers, were shipped to your facility. Please ensure the following:

- Review this letter for awareness and advice on action to be taken.
- Share this notice with the appropriate clinical staff at your site.
- No patient follow-up or notification is necessary.
- Return a completed **Customer Acknowledgment Form** to your Edwards TMTT Representative or via email to Edwards Customer Service at **XXXXXX**@edwards.com
- Return any impacted product to Edwards.
- Verify your impacted inventory and Customer Acknowledgement Form have been returned to Edwards within 15 days from receipt of this notification.

Distributors: Please notify your customers by sending this customer notification to any 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 has been 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 TMTT Representative.

Sincerely,

Brian Hudson
Senior Vice President, Quality
Edwards Lifesciences, Transcatheter Mitral and Tricuspid Therapies

URGENT FIELD SAFETY NOTICE
PRODUCT RECALL - ACTION REQUIRED
FCA # 179

Products: PASCAL Precision Transcatheter Valve Repair System
Model Number(s): 20000ISM and 20000IS
Serial Number(s): See Table in Acknowledgement Form
Basic-UDI Code: 0690103S004PAS000BC

CUSTOMER ACKNOWLEDGEMENT

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

This letter is being returned to confirm that we understand the information in the letter sent to us regarding the PASCAL Precision product that may be impacted by a manufacturing process that could result in the product not operating as intended.

Customer and Distributor Instructions:

Our records indicate that impacted product, as identified by their serial numbers, were shipped to your facility. Please ensure the following:

- Review this letter for awareness and advice on action to be taken.
- 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 TMTT Representative or via email to Edwards Customer Service at **XXXXXX**@edwards.com
- Return any impacted product to Edwards. Call Customer Service at **X-XXX-XXX-XXXX**, or email: **XXXXXX**@edwards.com to obtain a Returned Goods Authorization (RGA) number.
- Verify your impacted inventory and Customer Acknowledgement Form have been returned to Edwards within 15 days from receipt of this notification.
- 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 **XXXX** or your Edwards TMTT Representative with questions.

Model Number	Serial Number(s)	Customer PO	Received from Edwards (Yes/No)	Unit Used (Yes/No)	Unit to be Returned (Yes/No)
XXXX	XXXX	XXXX			

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