URGENT FIELD SAFETY NOTICE
PRODUCT ADVICE – ACTION REQUIRED
Edwards PASCAL Transcatheter Valve Repair System: 10000IS (Implant System) and 10000GS (Guide Sheath)
REF: FCA-133

< DD MMM YYYY>

<Physician Names>
<Hospital Name>
<Address>
<City/state/country/zip>

RE: PASCAL Transcatheter Valve Repair System

Attention: <Physician Names>,

This voluntary notice is being provided to inform you of an important update to the Instructions for Use (IFU) for the Edwards PASCAL Transcatheter Valve Repair System, affecting the following model numbers: 10000IS and 10000GS. Please note that no product return or rework is required as a result of this notification.

Description of the problem:

A potential procedural factor has been identified by Edwards, which may occur during the use of the PASCAL Transcatheter Valve Repair System. In a limited number of cases, observations of air bubbles have been made following insertion of the Implant System into the Guide Sheath. Although air bubbles are commonly observed during use of transcatheter devices, in at least one case it is believed that the introduction of air resulted in a coronary air embolism, which required medical intervention to stabilize the patient before successfully completing the PASCAL procedure. We are taking this opportunity to update the Instructions for Use (IFU) and physician training materials to add clarity around the minimum volume of aspiration required and specifics for de-airing tools.

Edwards

Affected Product:

Your current inventory of product is acceptable and safe for use. There is no need to return any product. Patients with previously implanted PASCAL devices are not affected by this action. Your Edwards representative can answer any questions you may have regarding the IFU updates, prior to the availability of the revised IFU in the packaged material. Once approved and translated, the updated IFU will be provided with future product shipments.

Advice on action to be taken by the user:

Preventive measures to ensure proper aspiration include utilization of a large volume syringe (50-60cc) to aspirate and flush the Guide Sheath with heparinized saline, after advancement of the Implant System and removal of the loader. The large volume syringe is to be used to aspirate a minimum of 45cc.

These measures are now described in the procedural training. The Instructions for Use (IFU) are being revised to include clarification of the appropriate prescribed aspiration tools and techniques, and highlighting a caution outlining that improper aspiration could lead to air embolism. Your Edwards field representative or clinical specialist will provide the necessary training to enable you and your team to become familiar with the updated IFU prior to formal availability.

We appreciate your review of this notification and request that you provide us with acknowledge of receipt. This notification has been communicated to the appropriate Regulatory Authorities.

We appreciate your attention, and apologize for the impact of this matter. If you have questions regarding the content of this notification, please contact your Edwards field representative, clinical specialist or Customer Service at <X-XXX-XXXX>.

Sincerely,

Gary I. Sorsher
Vice President, Quality
Transcatheter Mitral and Tricuspid Therapies

Edwards

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CUSTOMER ACKNOWLEDGEMENT

< DD MMM YYYY>

<Hospital Name>
<Address>
<City/state/country/zip>

This letter is being returned to confirm that we understand the information provided to us dated <DD MMM YYYY> related to the notification regarding proper de-airing of the PASCAL Transcatheter Valve Repair System. We have shared this information with all appropriate clinical staff at our site. We have also made the information available to personnel that may be using these devices as part of continuing communication and training.

Hospital / Location:

_____
Hospital Name, City, Country

Primary Operator:

_____
Print Name

_____
Signature Date

Please return this signed letter to your Edwards TMTT Representative or Customer Service by fax <XXX-XXX-XXXX> or email <XXXXXXXXXX> immediately after review