URGENT FIELD SAFETY NOTICE
– PRODUCT RECALL
Edwards PASCAL Transcatheter Valve Repair System
– Guide Sheath: 10000GS and 10000GSCE
REF: FCA-150

<XX November 2019>

<Physician Name>
<Hospital Name>
<Address>
<City/State/Country/Zip>

RE: Guide Sheath for Edwards PASCAL Transcatheter Valve Repair System

Attention: <Physician Name>,

Details on affected devices:

This notice is provided voluntarily to inform you of a product recall on the Guide Sheath (Model Number - 10000GS and 10000GSCE) used in conjunction with the Edwards PASCAL Transcatheter Valve Repair System. We are recalling all lots of this product at this time; a complete list of affected products is attached below.

Description of the problem:

It has been identified that there is a potential for damage to the inner liner of the PASCAL Guide Sheath due to a manufacturing issue. Based upon current information, the rate of this occurrence is approximately 0.5%, or 1 out of 200 units. There are no reports of patient adverse events or injury related to this occurrence, however it is possible embolization of a segment of the inner liner material could occur if a Guide Sheath with a damaged inner liner is used. There is no information to suggest that previously implanted patients are affected.

Advice on action to be taken by the user:

Do not use your current inventory of PASCAL Guide Sheaths; please return them to Edwards. Your Edwards TMTT Representative will assist with product return, and subsequent product replacement. Only the Guide Sheath is affected by this recall notice – not the entire PASCAL Transcatheter Valve Repair System.

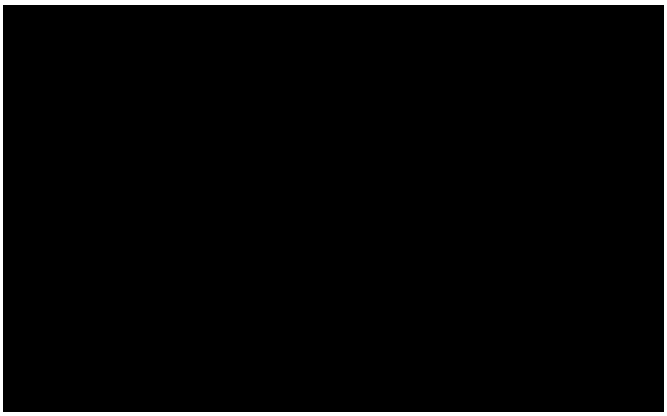
Customer Instructions:

- Please review this field safety notice and share information with appropriate clinical staff at your site.
- No patient follow-up or notification is necessary.
- Return completed Acknowledgment form.
- Return any impacted product.

Your assistance is necessary to ensure that this notice is reviewed and understood. 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 that have not been answered by this letter, please contact your Edwards TMTT Representative.

Sincerely,



Edwards

List of Affected Lot Numbers:

Commercial Lot Number
61809096
61846561
61960546
61972605
62022424
62022425
62149867
62149868
62202695
62225282
62249074
62249075
62249076
62354054
62429249
62556772
62718664
62718666

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CUSTOMER ACKNOWLEDGEMENT

< DD November 2019>

<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 recall notification of the PASCAL Guide Sheath. We have shared this information with all appropriate clinical staff at our site.

Hospital / Location: _____
Hospital Name, City, Country

Primary Operator: _____
Print Name

_____
Signature Date

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Recall Inventory Form

Note: Please indicate “NONE” if you do not have any inventory to return.

Model Number	Lot Number	Qty Received from Edwards	Number of Units Used	Number of Units to Be Returned

RGA Number: _____

Please return this signed letter to your Edwards TMTT Representative immediately by email at <XXXXX@Edwards.com> or by fax at <XXXXXXXXXX>.