Edwards

URGENT FIELD SAFETY NOTICE
Reference: FCA-140

Edwards CENTERA Transcatheter Heart Valve System
Model Numbers: 9551S23, 9551S26, 9551S29
Lot Numbers: All lots for models listed

ACTION REQUIRED

<MM DD, YYYY>

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

ATTENTION: Risk Management and Users of the Edwards CENTERA Transcatheter Heart Valve System

Details on affected device:
Edwards CENTERA Transcatheter Heart Valve System
Models: 9551S23, 9551S26, 9551S29

Dear Customer,

Edwards has received reports of difficulty tracking and manipulating the CENTERA system around the aortic arch that have resulted in vascular injury including aortic dissection and death during early cases. A thorough investigation of these reports concluded that tracking difficulty is more likely to occur when the device is used in specific tortuous aortic anatomies. The observed incidence of serious events related to this issue is approximately 1.50% based on the limited global experience with this device to date.

These specific anatomies include those with multiplanar curvature of the aorta, in which alternate treatment options should be considered, and those with extremely dilated innominate trunks or acute angulation of the aortic arch, in which it is recommended to use a stiffer guidewire to avoid tracking difficulties.

A CTA of the chest-abdomen-pelvis may be necessary to properly assess the ascending, transverse and descending aorta. This assessment ensures the aorta is suitable to

accommodate the delivery system distal stiff section and that the aorta is free from tortuosity or disease which may prevent the safe usage of the CENTERA system.

Edwards advises to follow the guidelines and instructions provided in the Edwards CENTERA Transcatheter Heart Valve System training materials for device use highlighted below and the following instructions will be added to the IFU:

- A stiffer guidewire is recommended in anatomies with extremely dilated innominate trunks or acute angulation of the aortic arch to avoid tracking difficulties which may lead to vascular injury including aortic dissection.

- For anatomies with extreme aortic tortuosity, including multiplanar curvature, consider use of alternate treatment options which do not have a stiff distal section of the catheter (e.g. balloon expandable transcatheter valve replacement) in order to avoid tracking difficulty that could lead to vascular injury including aortic dissection.

If significant resistance or difficulty is encountered while tracking around the arch or crossing the native annulus, discontinue use of the device and remove the system as a single unit while maintaining guidewire position. Similarly, remove the system if it is kinked or damaged during use.

Please review the acknowledgment form, sign and date it, and return it to your Edwards Representative or FAX/email it as instructed on the form attached. There is no further action necessary regarding this Field Safety Notice.

This notice should be provided to all users of the CENTERA system within your organization. If you have any questions or concerns regarding this Urgent Field Safety Notice, please do not hesitate to contact your Edwards Representative.

Sincerely,

[redacted]

Edwards Lifesciences

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

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Acknowledgment Form

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I acknowledge that I have read and understand the information provided in the Urgent Field Safety Notice dated [DATE OF LETTER] regarding Edwards CENTERA Transcatheter Heart Valve System, Models 9551S23, 9551S26, 9551S29.

Hospital / Location (Print):

_____

Name (Print):

_____

Title and Department:

_____

Contact Information
Tel.No/Fax No /Email:

_____

Signature: _____

Date: _____

Please email or fax this acknowledgement form to the attention of:
Customer Service
[insert local EW company name]
[insert local EW company address]
[insert local Customer Service email address]
[insert local Customer Service fax number]