St. Jude Medical
1 St. Jude Medical Drive
St. Paul, MN 55117 USA
Tel 651-756-2000

Urgent Medical Device Notice

Portico™ Re-Sheathable Transcatheter Aortic Valve System
All Model Numbers, All Serial Numbers

12 September 2014

Cath Lab Manager/Risk Manager
Account Name
City, State, Zip

Dear Valued Customer,

Effective, September 12, 2014, St. Jude Medical has temporarily suspended all commercial and investigational implants for the Portico™ Re-Sheathable Transcatheter Aortic Valve System device worldwide.

Specifically, we have received a small number of reports of reduced valve leaflet mobility identified in the U.S. IDE study. These reports came to our attention as a result of a review of 4D (cardiac motion) CT scans performed 30 days after implant in the study. We have not received reports of valve areas or gradients in the U.S. IDE clinical program that are outside of the normal ranges for our TAVR devices. Additionally, to date, the worldwide TAVR adverse event rates remain low and are consistent with event rates cited in medical literature.

The Company has launched a comprehensive analysis of potential causes for the leaflet mobility imaging findings and will communicate the results and any recommendations as soon as possible. While our evaluation is underway, St. Jude Medical is taking a conservative approach by pausing all implants of this device.

St Jude medical is requesting that you cease implants of the Portico™ Re-Sheathable Transcatheter Aortic Valve System, until further notice and place all valves in quarantine. Please continue to follow-up with patients as normal.

St. Jude Medical is committed to providing the highest quality products and support. We apologize for any inconvenience this action may cause you, and we appreciate your understanding as we take action to ensure patient safety.

If you have any questions or concerns, please contact your St. Jude Medical Sales Representative.

Thank you for your continued support.

Sincerely,

Roland Gerard
Vice President, EMEA Regulatory Affairs, ID Quality
St. Jude Medical