Urgent Field Safety Notice

Navitor™ Transcatheter Aortic Heart Valves

Models: NVTR-27, NVTR-29, NVRO-27, NVRO-29, NVRO-35

FA-Q424-SH-1

October 2024

Dear Valued Customer,

Abbott is voluntarily recalling a total quantity of twenty-seven (27) Navitor™ Transcatheter Aortic Heart valves which are impacted by a manufacturing issue (referred to as "Impacted Valves"). You are receiving this letter because our records indicate that you have received Impacted Valve(s) listed in Appendix A. While we continue to investigate this issue, we are initiating a product retrieval of the Impacted Valves if they have not been implanted. All other Navitor™ valves in your inventory are not affected and can continue to be used.

As background, an error was identified in the manufacturing step used to measure leaflet deflection. This measurement error led to the acceptance of a limited number of valves with a leaflet deflection value that was outside of its established specifications. Deflection is a mechanical property of bioprosthetic leaflets which characterizes leaflet stiffness. The effect of this was utilizing leaflets that were less stiff. The use of lower-than-expected stiffness of such leaflets could potentially affect long-term durability of the Impacted Valve. Decreased stiffness of the leaflets is theorized to cause potential valve failure due to increased interactions between the valve leaflets and the stent frame and/or inner skirt. To date, there have been no complaints associated with the Impacted Valves.

For the valve(s) listed in Appendix A that have been implanted, Abbott believes that the risk of early failure is remote based on the results of internal quality tests performed on these valves during manufacturing. This testing included visual and dimensional inspections as well as hydrodynamic testing and an assessment of leaflet coaptation. Regarding the potential risk of long-term adverse outcomes, Abbott has assessed this risk as remote. The potential long-term adverse outcomes may include acute bioprosthetic valve regurgitation and/or later bioprosthetic valve failure due to progressively worse regurgitation or stenosis. Abbott is executing further testing to verify that long-term durability of the Impacted Valves has not been affected and will communicate any changes to the recommendations set forth in this letter if needed by Q4 2025. In the interim, Abbott recommends continuing the same local standard of care in patients implanted with the Impacted Valve as would be used with patients implanted with any other transcatheter aortic valve implant.

Steps Abbott is Requesting You to Take:

- Return any remaining unused Impacted Valves listed in Appendix A. Your Abbott representative will assist you in this activity and will facilitate inventory replenishment.
- Complete and return the accompanying Acknowledgement Form to Abbott.

Abbott is informing all applicable regulatory agencies about this matter. Please report any adverse reactions or quality problems experienced with the use of these products to Abbott.

We sincerely apologize for any inconvenience that this may cause. Please know that Abbott is committed to providing the highest level of support, and we thank you for assisting us with this process.

Sincerely,

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart