

November 17, 2020

Dear Patient:

On November 17, 2020, Boston Scientific announced a voluntary recall of the LOTUS Edge Aortic Valve System due to the complexities of the delivery system that occur during the implant procedure. At this time, there are no known safety concerns for patients who have a LOTUS or LOTUS Edge valve implanted. These implanted valves continue to show clinically effective performance post-implant.

Patients who have a LOTUS or LOTUS Edge valve implanted should continue with their routine follow-up care. There is no need additional need for action.

Thank you.



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