On-X® | Aortic Heart Valve
STEP AHEAD

Subject: FDA Approval for Significantly Reduced Anticoagulation Therapy

Important Anticoagulation Information for On-X Aortic Valve Recipients

Dear On-X Aortic Valve Recipient:

This information is for patients who have received an On-X Aortic Heart Valve specifically in the aortic position. This content is intended for On-X Aortic Valve recipients only.

The On-X Aortic Valve received FDA approval in 2015 for significantly reduced anticoagulation therapy. In consultation with your physician, On-X Aortic Valve recipients may now be able to reduce their target INR range to 1.5 – 2.0 after 3 months standard anticoagulation therapy.[1]

Any changes in your anticoagulation regimen need to be determined by your physician based on your specific health condition and history. This notification does not supersede advice you receive for anticoagulation therapy from your physician or health care professional.

Please take this information with you to discuss with your physician. If you or your physician have any questions or concerns regarding this information, please feel free to call or email a representative at the contact information below based on your applicable region.

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The physician should be aware of the following potential adverse events and discuss these with the On-X Aortic Valve recipient:
POTENTIAL ADVERSE EVENTS: Adverse events potentially associated with the use of prosthetic heart valves (in alphabetical order) include, but are not limited to: angina, cardiac arrhythmia, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, myocardial infarction, prosthesis leaflet entrapment (impingement), prosthesis non-structural dysfunction, prosthesis pannus, prosthesis perivalvular leak, prosthesis regurgitation, prosthesis structural dysfunction, prosthesis thrombosis, stroke, and thromboembolism. It is possible that these complications could lead to: reoperation, explantation, permanent disability, or death.
1. On-X Prosthetic Heart Valve Instructions for Use.

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