

On-X[®]
STEP AHEAD

Aortic
Heart Valve

Patient Information

The Only Mechanical Aortic Valve
FDA Approved Requiring Less
Blood Thinner*



*After 3 months of standard therapy.
See Instructions for Use for full details.¹



CryoLife[®]
Life Restoring Technologies[®]

For patients less than 70 years of age requiring an aortic heart valve replacement, the following two pages are an overview of the **2017 American Heart Association Guidelines** to help inform your choice.²

Shared Decision: The choice of the type of heart valve a patient receives is a shared decision among the patient and medical professionals. The patient's overall condition and preferences should be considered.

<50 Years



For Patients Less than 50 Years:



Mechanical Valve – is the favored choice for patients less than 50 years.[^]

On-X Aortic Valve – is the only mechanical valve that is FDA approved requiring less blood thinner* with the additional benefit of less bleeding risk compared to the standard blood thinner therapy required for all other mechanical aortic valves.^{1,2}



Bioprosthetic (Tissue) Valve - is recommended for any age patient for whom blood thinner therapy (warfarin) is not indicated, cannot be managed appropriately, or is not desired.

*After 3 months of standard therapy.¹

[^]Unless blood thinner (warfarin) is not desired, cannot be monitored, or is contraindicated.



50-70 Years

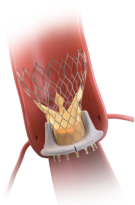


For Patients 50 to 70 Years:

Mechanical[^] or Bioprosthetic (Tissue) Valve – either choice is reasonable.



Other Factors



Valve in Valve (VIV): For patients who require an aortic valve replacement for a failing tissue valve, a less invasive VIV procedure can place a new tissue valve inside your failing tissue valve.

Note: VIV is neither a long-term proven therapy, nor a reasonable option for the majority of tissue valve patients due to the size of their existing valve² being too small, and as a result restricting blood flow.^{3,4}

Mechanical vs. Bioprosthetic (Tissue) Valves

A patient's choice regarding whether to receive a mechanical or tissue heart valve replacement includes weighing the major advantages and disadvantages of both valve types² (see Table 1).

Risk of Reoperation:

- The primary advantage of mechanical valves is the likelihood of lasting a patient's lifetime without the need for another valve operation because the valve has worn out.^{2,5}
- The primary disadvantage of tissue valves is their tendency to wear out (Fig. 1) and require replacement, especially in patients less than 65 years old.^{5,6}

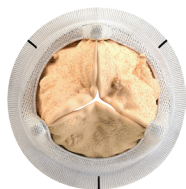






Fig. 1. Image of a calcified tissue valve that is worn out.

Risk of Bleeding:

- The primary advantage of tissue valves is that they usually do not require long-term blood thinner therapy (e.g., warfarin).² However, approximately one-third of patients with a tissue valve do not benefit from this, because of a blood thinner (e.g., warfarin) requirement for other heart or vascular conditions (e.g., atrial fibrillation and deep venous thrombosis).⁷
- The primary disadvantage of mechanical valves is the requirement for blood thinner (warfarin) therapy, with its accompanying lifelong risk of bleeding, complying with blood thinner therapy and lifestyle requirements (e.g., regular blood tests, daily medication, consumption of leafy greens).²

Table 1: Tissue vs. Mechanical Heart Valve – Valve Lifetime, Blood Thinner, Bleeding Risk, and Survival.

	Tissue Valve	Mechanical Valve	Summary
Valve Lifetime (years) ^{5,6} 	Patients <65 years: 14.5 Patients >65 years: 21.4	All ages: Likelihood of a lifetime	Mechanical valves are likely to last a lifetime, but tissue valves wear out especially in patients <65 years.
Blood Thinner ^{2,7} 	Short term warfarin therapy (3 to 6 months) and lifelong daily aspirin	Lifelong daily aspirin and warfarin	Both mechanical and tissue valves require aspirin. Mechanical valves also require warfarin, and 1/3 of tissue valves may require additional blood thinner (e.g. warfarin). On-X Aortic Valve is the only mechanical valve FDA approved requiring less warfarin.*
Bleeding (% per patient year, >30days) ⁸⁻¹⁶ 	0.4 to 1.9	0.7 to 2.5 [†]	Both mechanical and tissue valves have risks of bleeding, but the risk is typically higher for mechanical valves.
Survival ^{2,18,19} 	Some studies report mechanical valves having a survival advantage compared with tissue valves in patients aged 50-69 years; whereas other studies show no advantage. Data are still inconclusive regarding a survival advantage for mechanical vs. tissue valve replacement in this age group.		

[†]Using all bleeding rates from Aortic or Mitral valves (no double valves). These data were collected from FDA-reviewed sources. Patients who are advanced in age (>65 years) have a higher risk of bleeding while taking warfarin.¹⁷

*After 3 months of standard therapy.¹

On-X

Patient Stories



Fred Hoiberg, Age 43

Head Coach: Chicago Bulls

On-X Aortic Valve Recipient

"I now have the On-X Aortic Valve, and I'm not worried that I'll need a reoperation since mechanical valves typically last a lifetime. Taking blood thinner with my On-X Valve is not a big deal, and it doesn't slow me down."



Michael, Age 56

Senior Physician Assistant -
Clinical, Mayo Clinic

On-X Aortic Valve Recipient

"Being my age of 56, I decided I was going to go [with an On-X] mechanical [Valve] because I didn't want to have another operation in 15 years" which is not unusual with a tissue valve in younger patients.

Note: Outcomes may vary per patient.

On-X Patient Stories (continued)



Virginia, Age 65

Author

On-X Aortic Valve Recipient

"Once I was satisfied with what I knew about the On-X Valve, I told my surgeon that it had to be the On-X Valve, or I wasn't going to have the surgery. I'm so thrilled that I did not get the tissue valve. After having gone through this extensive surgery, I would not want to have to go through it again."

"[...] The balance between valve durability [or lifetime] versus risk of bleeding and thromboembolic events favors the choice of a mechanical valve in patients <50 years of age[...]" A mechanical aortic valve is reasonable in patients ≤70.

2017 **American Heart Association**
Guidelines²

Note: Outcomes may vary per patient.



Aortic
Heart Valve

Ask your doctor if the
On-X Aortic Valve is right for you.

Watch and Learn More at:

 HeartValveChoice.com

Call: 888-692-7897

Email: info@HeartValveChoice.com

1. On-X Prosthetic Heart Valve Instructions for Use with INR 1.5-2.0. 2. Nishimura R et al., Circulation. 2017;135:e1159-95. 3. Dvir D et al., JAMA. 2014;312(2):162-70. 4. IMS US Sales Report, Q4, 2010 to Q3, 2016. Perimount models 2700, 2800, and 3300. Report run by CryoLife Marketing, 04/10/2017. Data on file. 5. van Geldorp M et al., J Thorac Cardiovasc Surg. 2009;137:881-6. 6. Wang M et al., Ann Thorac Surg 2017 ;pii: S0003-4975(17)30266-7. 7. Briffa N and Chambers J Circulation. 2017;135:1101-3. 8. On-X Prosthetic Heart Valve Instructions for Use. 9. Edwards Life Sciences Carpentier-Edwards PERIMOUNT Magna Pericardial Aortic Bioprosthesis Model 3000TFX Aortic Instructions for Use. 10. Edwards Life Sciences Carpentier-Edwards PERIMOUNT Magna Ease Pericardial Aortic Bioprosthesis Model 3300TFX Instructions for Use. 11. Edwards Life Sciences Carpentier-Edwards PERIMOUNT Theon Mitral Pericardial Aortic Bioprosthesis Model 6900PTFX Instructions for Use. 12. Medtronic Mosaic Porcine Bioprosthesis with Cinch Advanced Implant System Instructions for Use. 13. St. Jude Medical Trifecta Valve Instructions for Use. 14. St. Jude Medical Physician's Manual Mechanical Heart Valve. 15. CarboMedics Prosthetic Heart Valve Instructions for Use. 16. Medtronic Open Pivot Heart Valve Instructions for Use. 17. Coumadin Labeling on FDA website. http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/009218s1081b1.pdf, downloaded on 05/24/2016. 18. Glaser N et al., Euro Heart J. (2016)37, 2658-67. 19. Zhao DF et al., Ann Thorac Surg 2016;102:315-27.

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