

**On-X<sup>®</sup>**  
STEP AHEAD

Aortic  
Heart Valve

## Patient Information

The Only Mechanical Aortic Valve  
FDA Approved For Significantly  
Less Anticoagulation\*



\*After 3 months of standard therapy.  
See Instructions for Use for full details.<sup>1</sup>



**CryoLife<sup>®</sup>**  
Life Restoring Technologies<sup>®</sup>

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.<sup>2</sup>

**Shared Decision:** Choosing 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.<sup>^</sup>

**On-X Aortic Valve** – is the only mechanical valve that is FDA approved for significantly less anticoagulation\* with the additional benefit of >60% less bleeding risk compared to the standard anticoagulation therapy required for all other mechanical aortic valves.<sup>1,2</sup>



**Bioprosthetic (Tissue) Valve** – is recommended for a patient of any age for whom anticoagulation therapy is not indicated, cannot be managed appropriately, or is not desired.

\*After 3 months of standard therapy.<sup>1</sup>

<sup>^</sup>Unless anticoagulation is not desired, cannot be monitored, or is contraindicated.



50-70 Years

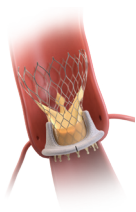


**For Patients 50 to 70 Years:**

**Mechanical<sup>^</sup> or Bioprosthetic (Tissue) Valve** – either choice is reasonable.



## Other Factors



**Transcatheter Aortic Valve Replacement (TAVR) Valve in Valve (VIV):** This is an aortic valve replacement procedure in which a new tissue valve is placed inside a failing tissue valve.

**Note: TAVR 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 valve<sup>2</sup> being too small, and as a result, restricting blood flow.<sup>3,4</sup>**

# Mechanical vs. Bioprosthetic (Tissue) Valves

A patient's decision regarding heart valve replacement includes whether to receive a mechanical or tissue valve, which may include the considerations below.<sup>2</sup>

## Risk of Reoperation:

- Mechanical valves are likely to last a patient's lifetime without the need for another valve operation due to the valve wearing out.<sup>2,5</sup>
- Tissue valves have a tendency to wear out (Fig. 1) and can require replacement as early as 5 years, especially in patients less than 65 years old.<sup>5,6</sup>

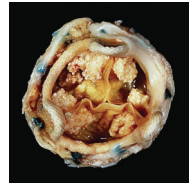


Fig. 1. Image of a calcified tissue valve that is worn out.




## Risk of Bleeding:

- Tissue valves usually do not require long-term anticoagulation therapy.<sup>2</sup> However, up to one-third of patients with a tissue valve require anticoagulation for other heart or vascular conditions (e.g., atrial fibrillation and deep venous thrombosis).<sup>7</sup>
- Mechanical valves require anticoagulation therapy.

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\*After 3 months of standard therapy.<sup>1</sup>

## Mechanical vs. Tissue Heart Valve: Valve Durability, Anticoagulation, and Survival

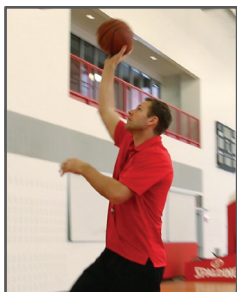
	Mechanical Valve	Tissue Valve	Summary
Valve Durability <sup>5,6</sup> 	All ages: Likely to last a lifetime.	Patients ≤65 years: Valve failure as early as 5 years <sup>‡</sup>	Mechanical valves are likely to last a lifetime, but tissue valves wear out especially in patients ≤65 years.
Anticoagulation Therapy <sup>2,7,†</sup> 	Daily lifelong anticoagulation therapy	Short term anticoagulation therapy (3 to 6 months) with potential for daily lifelong therapy due to other conditions	Mechanical valves require anticoagulation. Up to 1/3 of tissue valves may require anticoagulation. <b>On-X Aortic Valve is the only mechanical valve FDA approved for significantly less anticoagulation.*</b>
Survival <sup>8</sup> 	From one study by Glaser et al., long-term survival was significantly better in patients aged 50 to 69 years who had a primary isolated aortic valve replacement with a mechanical valve than with a tissue valve.		

\*After 3 months of standard therapy.<sup>1</sup>

‡ The average time before tissue valve failure is 14.5 years with a standard deviation of 4.4 years.<sup>6</sup>

†Aspirin is recommended for mechanical valves and is considered reasonable for tissue valves.

# On-X Patient Stories

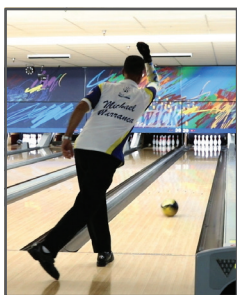


## **Fred Hoiberg, Age 43**

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  
Professional Bowler

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..." which is not unusual with a tissue valve in younger patients. In addition to being a Senior Physician Assistant, Michael is a professional bowler and stays active.*

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 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  $\leq 70$ .**

2017 **American Heart Association**  
Guidelines<sup>2</sup>

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](http://HeartValveChoice.com)

Call: 888-692-7897

Email: [info@HeartValveChoice.com](mailto:info@HeartValveChoice.com)

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 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;104:1080-87. 7. Briffa N and Chambers J *Circulation*. 2017;135:1101-3. 8. Glaser N et al., *Euro Heart J*. 2016;37:2658-67.

Fred Hoiberg is a paid consultant of CryoLife.

On-X Life Technologies, Inc.  
1300 East Anderson Lane, Bldg. B  
Austin, Texas 78752 USA  
Phone: (512) 339-8000  
Fax: (512) 339-3636  
Email: [onx@onxlti.com](mailto:onx@onxlti.com)

CryoLife, Inc.  
1655 Roberts Boulevard, NW  
Kennesaw, Georgia 30144 USA  
Phone: 888-427-9654  
Fax: 770-590-3753  
Email: [CUSTSVC@cryolife.com](mailto:CUSTSVC@cryolife.com)

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