



# CryoLife, Inc.

*Pat Mackin*

*Chairman, President and Chief Executive Officer*



**CryoLife®**  
Life Restoring Technologies®

# Forward Looking Statement

Statements made in this presentation that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect the views of management at the time such statements are made. These statements include those regarding the ability of CryoLife's product portfolio to drive profitable growth; the ability of the On-X acquisition to accelerate growth and expand gross margins; the expected growth of the market for our aortic heart valves due to demographics and device adoption; our expectation that there will be additional upside for our product sales in France as we leverage direct sales of our full product portfolio in France; our ability to expand our sales of BioGlue in Japan as a result of receiving in 2015 an expanded indication for BioGlue for use in thoracic aneurysm, Bentall & LVAD procedures; our expectations regarding our ability to execute on our clinical trial for BioGlue in China and the timeline for that clinical trial; our expectations regarding the ability of the On-X transaction to enhance our growth profile, increase opportunities for cross selling, drive margin expansion, provide CryoLife with a new addressable market opportunity of \$220MM, generate highly attractive margins, facilitate increased adoption of On-X portfolio penetration, enhance and leverage our existing direct sales organization, and strengthen our strategic focus on aortic and mitral valve repair and replacement surgery; the ability of the INR indication for the On-X valve of 1.5 to 2.0, to be a significant differentiator, distinct competitive advantage and catalyst for us to achieve market leadership in the mechanical heart valve market; our belief that compelling clinical data regarding the On-X valve supports future growth; the anticipated benefits for our business development program; and our beliefs regarding our expectations for financial performance in 2017. These forward-looking statements are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for year ended December 31, 2016. CryoLife does not undertake to update its forward-looking statements.

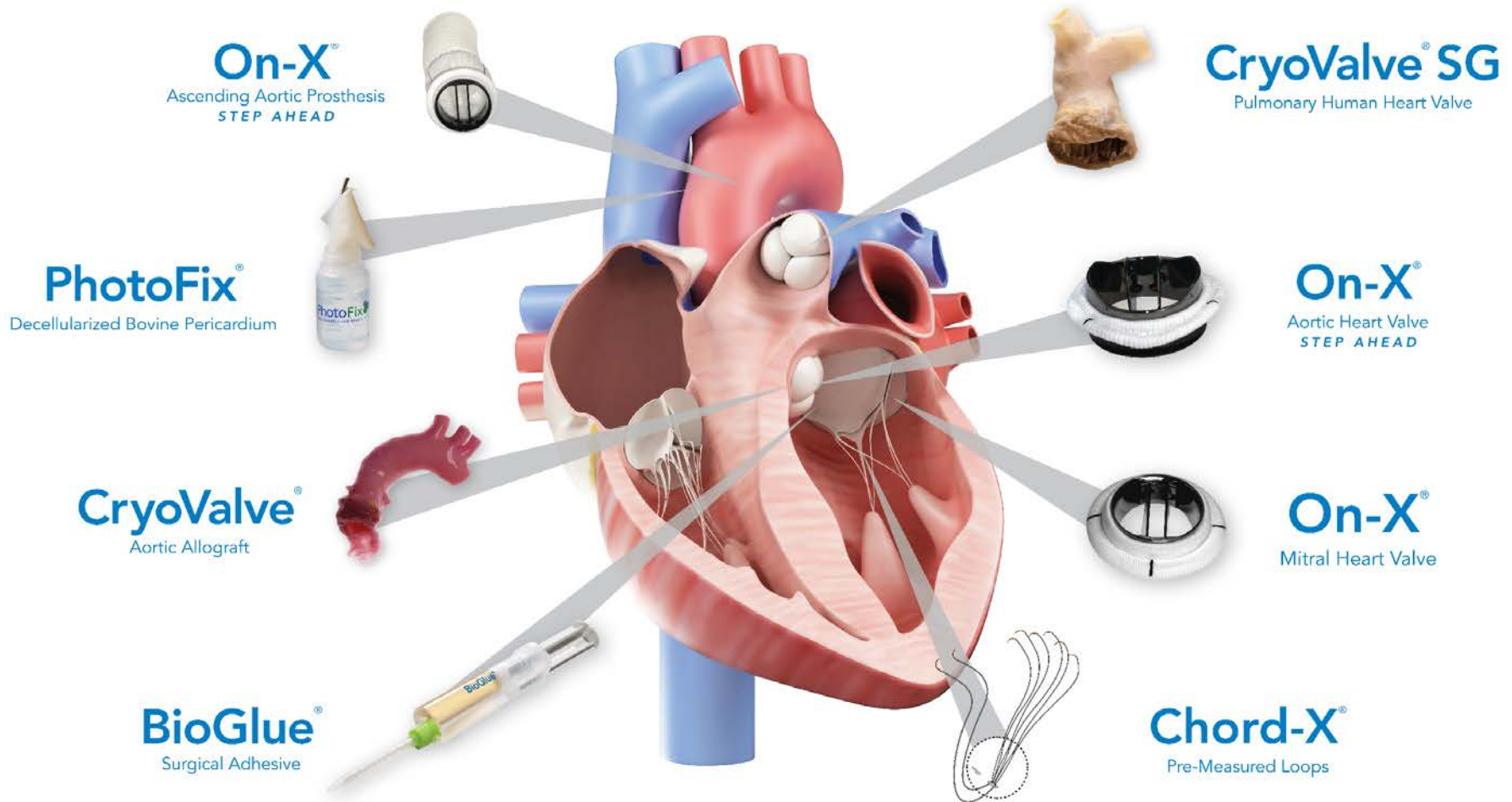
# CryoLife Mission Statement

- CryoLife helps surgeons restore lives by providing the highest quality tissue services and medical devices.
- We strive to develop our people by promoting a culture of quality, transparency, and integrity.
- By doing so, we deliver value to our shareholders, our employees, and our community.



*Become a leader in providing unique and differentiated technologies and solutions to patients with structural heart disease that will improve clinical outcomes as well as reduce the overall cost to the healthcare system*

# Cardiovascular Technology Business





# Allograft Tissues and Largest Product Lines

## Cardiac Allografts



37% of Revenue

## On-X<sup>®</sup> Prosthetic Heart Valves *STEP AHEAD*



20% of Revenue

## BioGlue<sup>®</sup> Surgical Adhesive



35% of Revenue

Note: Percentage revenues calculated based on pro forma 2016 revenues

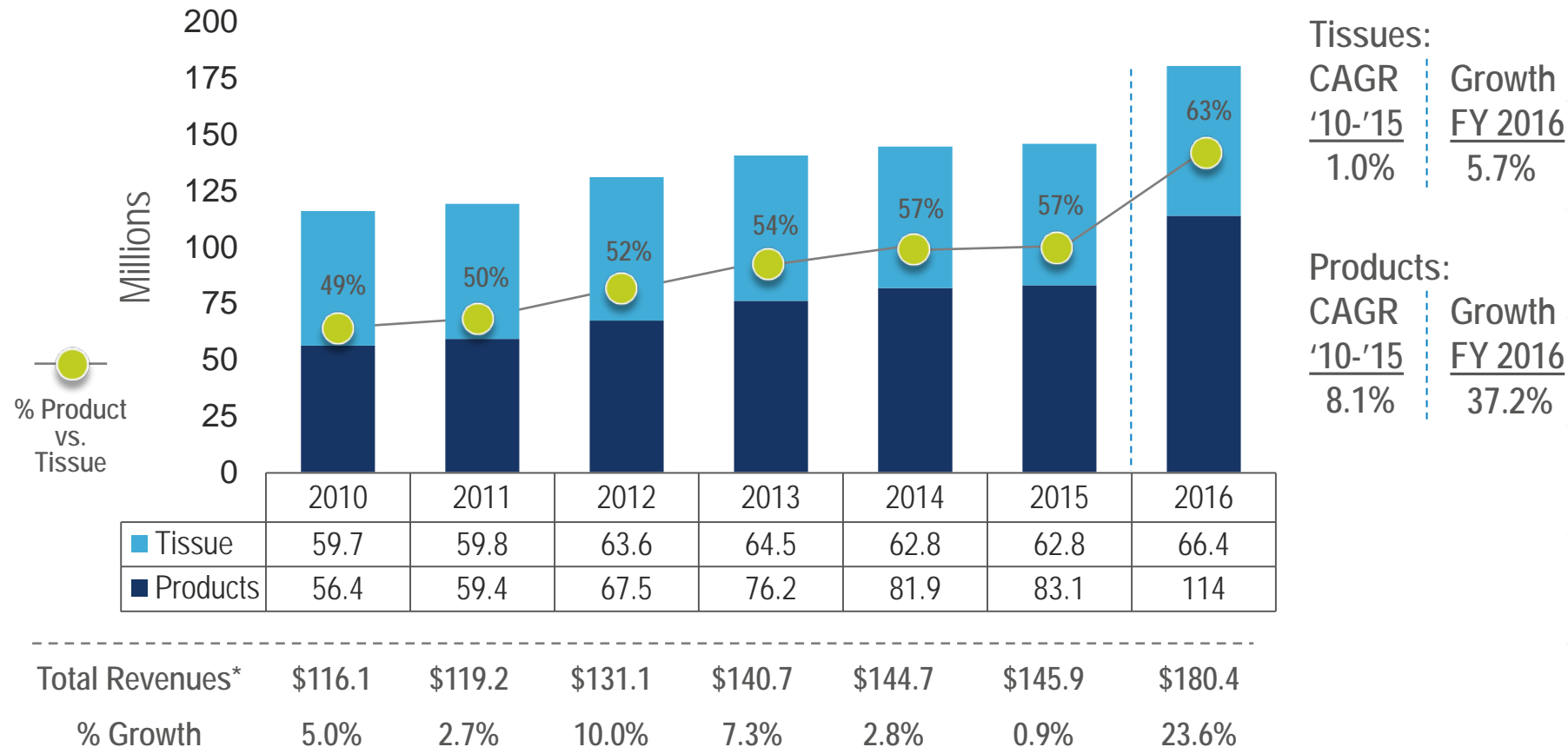
# Investment Rationale

- **Established Product Portfolio Driving Profitable Growth**
- **On-X Acquisition Accelerates Growth and Margin Expansion**
- **Highly Experienced Direct Sales Organization**
- **Proven Leadership**
- **Active Business Development Program**

# Tissue and Product Revenues

## Mix Shift from Tissues to Higher Margin Devices (Products)

- 2010 – 2015 revenue growth of 4.7% (CAGR) and significant M&A in 2016



Note: Total revenues excluding grant revenue. 2016 revenues reflect On-X Acquisition and of HeRO and ProCol. [Pro forma revenues adjusted for On-X acquisition and disposals of HeRO and ProCol.]

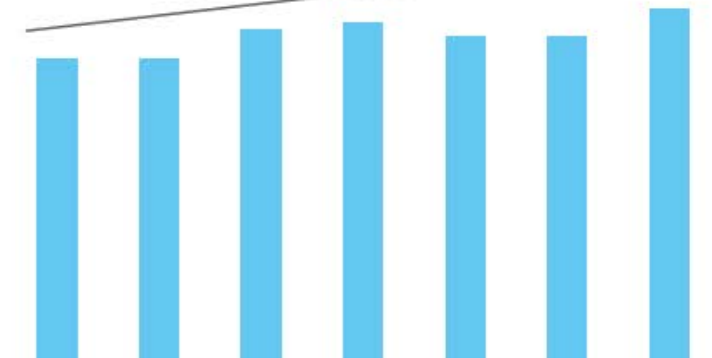


# CryoLife Products- Cryopreserved Tissue

## Cryopreserved Tissue: Five-Year Tissue Revenue

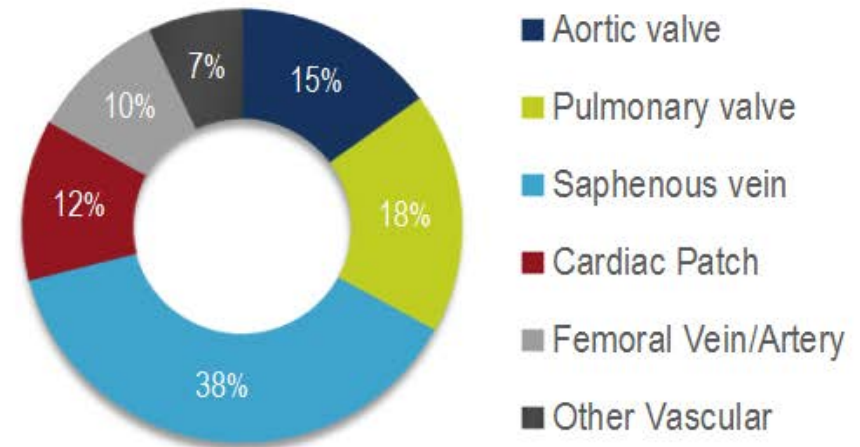
### Revenue

CAGR 1.8%



	2010	2011	2012	2013	2014	2015	2016
Revenue	\$59.7	\$59.8	\$63.6	\$64.5	\$62.8	\$62.8	\$66.4

### Business Mix



### Products



Pulmonary Valve



Aortic Valve



Saphenous Vein



Cardiac Patch

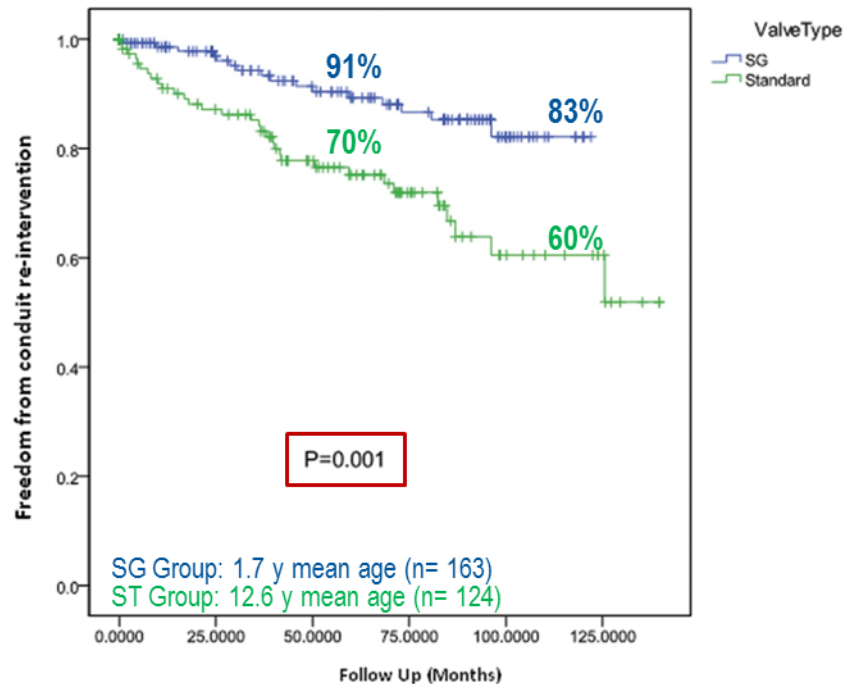
# Pulmonary Valve Homografts

## CryoValve® SG Pulmonary Valves



### SynerGraft® Decellularized Technology

- + Eight published papers with >2,500 patient years follow-up
- + 10 year actuarial freedom from explant = 93%<sup>1</sup>
- + 10 year actuarial freedom from reintervention = 83%<sup>2</sup> (see plot)
- + Over 30,000 pulmonary valves implanted since 1984<sup>3</sup>
- + Over 6,300 SG pulmonary valves implanted since 2000<sup>3</sup>

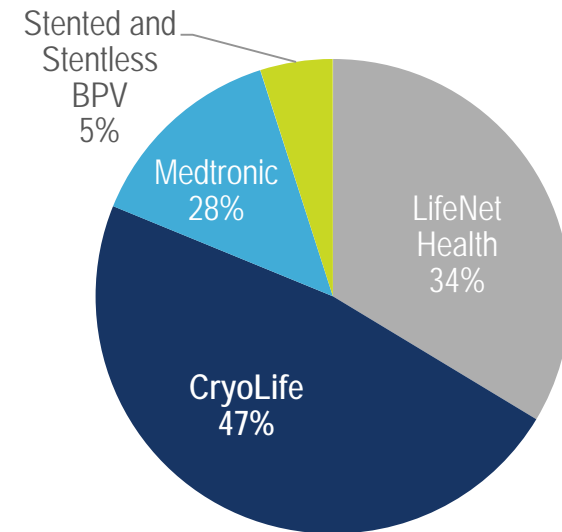


### US Pulmonary Valve Replacement Market:

2,300 procedures

Market Size = \$24M

2% CAGR



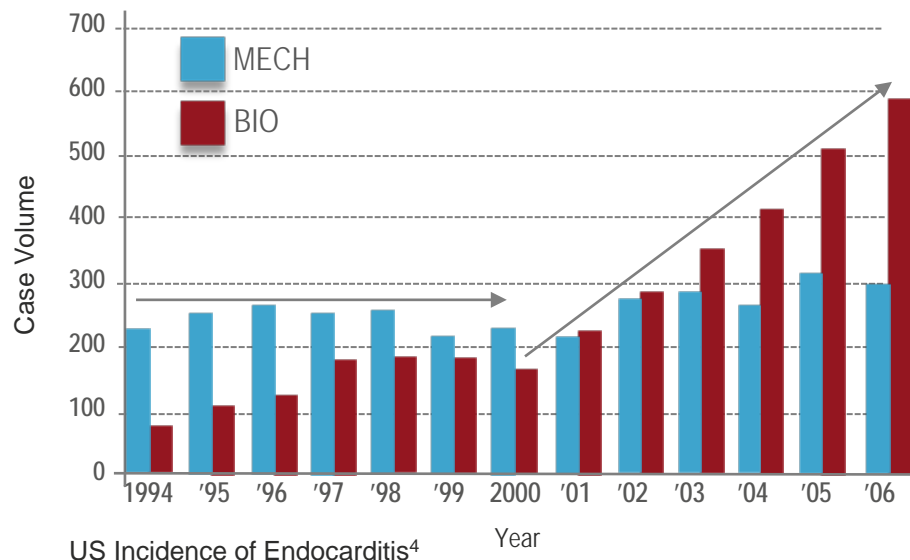
# Aortic Valve Homografts

## CryoValve® Aortic Heart Valves



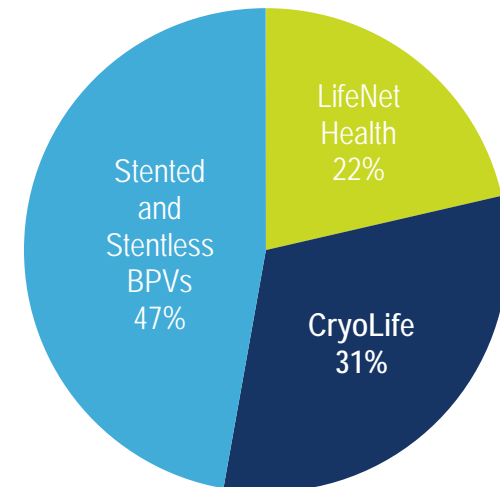
### Society of Thoracic Surgeons Recommendation<sup>1</sup>

- **Class I** - Homograft replacement of the aortic root should be considered for patients with extensive active endocarditic destruction of the aortic annulus. **(Level of evidence B)**
- **Class IIa** - Homograft replacement of the aortic valve can be considered for patients with endocarditis without annular destruction, especially when the potential for reinfection is elevated. **(Level of evidence B)**
- **95% freedom from recurrent endocarditis at 10 years<sup>2,3</sup>**
- **Growing market due to demographics and device adoption (TAVR)**



### US Aortic Valve Replacement due to Endocarditis Market:<sup>5</sup> 3,200 procedures

Market Size = \$22.5M  
9% CAGR



# Saphenous Vein Homografts

## CryoVein® Saphenous Vein

- High limb salvage rates: 70% at 4 years<sup>2</sup>
- Excellent resistance to infection<sup>6</sup>
- Provides natural suturability and compliance<sup>3</sup>

## Clinical Effectiveness

Reported Limb Salvage Rates for CryoVein Used in Peripheral Bypass						
Author	n	% redo	1 yr	2 yr	3 yr	4 yr
Randon, et al <sup>1</sup>	92	62%	85%	77%	70%	NR
CryoLife Multicenter <sup>2</sup>	381	59%	73%	72%	70%	70%
Martin, et al <sup>3</sup>	82	94%	84%	81%	NR	62%
Farber, et al <sup>4</sup>	177	50%	80%	71%	NR	NR
Buckley, et al <sup>5</sup>	24	27%	80%	80%	NR	NR

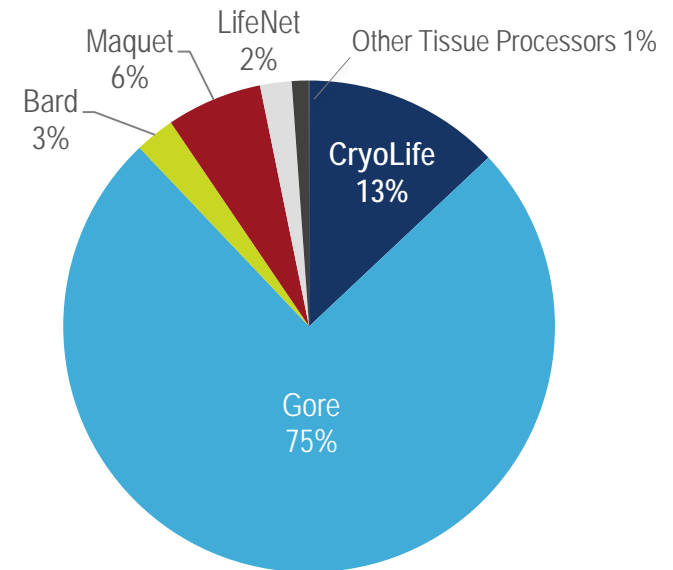
Note: Market procedures, share, size, and CAGR are approximate annual U.S. numbers based on actual CryoLife data and market reports, including iData and IMS.

1. Randon C, et al. J Vasc Surg 2010;51:869-77;
2. CryoLife data on file (ML0041);
3. Martin R, et al. Ann Surg 1994;219:6:664-72;
4. Farber A, et al. J Vasc Surg 2003;38:15-21;
5. Buckley C, et al. J Vasc Surg 2000;32:731-8;
6. Fujitani, et al. J Vasc Surg 1992;15-519-25.



**US Below the Knee Bypass Market:**  
22,000 procedures (BTK)

Market Size = \$182.5M  
1.4% CAGR



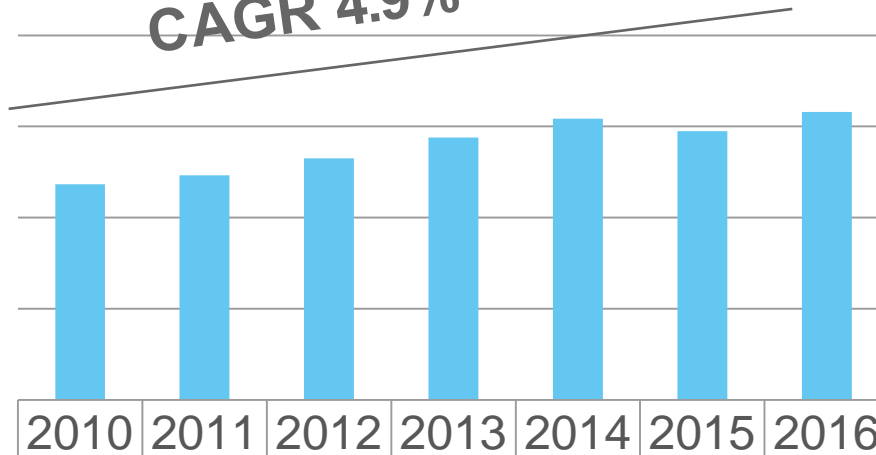
# CryoLife Products - BioGlue Sealant

## BioGlue Surgical Sealant



### Revenue

CAGR 4.9%<sup>†</sup>



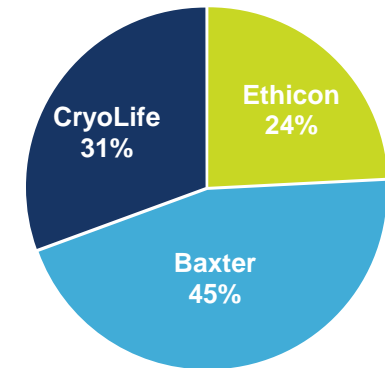
■ Revenue	\$47.3	\$49.3	\$53.0	\$57.6	\$61.7	\$59.0	\$63.2
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### US Cardiovascular Sealant Market:

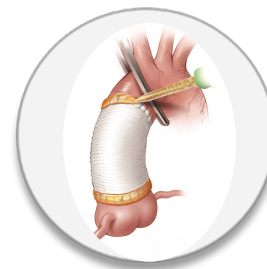
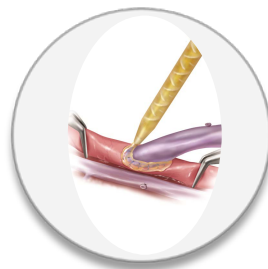
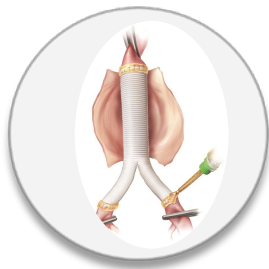
145,000 procedures

Market Size = \$112.2M

3% CAGR



### BioGlue Indications



# Global Expansion

## Direct in France - 2015

- Nominal revenue from France January-September 2015 as distributor sold off inventory
- June 22nd announced agreement with French distributor to take business direct on October 1st, 2015
- 2014 revenue of BioGlue and PerClot was \$3 million
- Additional upside as we leverage direct sales of the full product portfolio

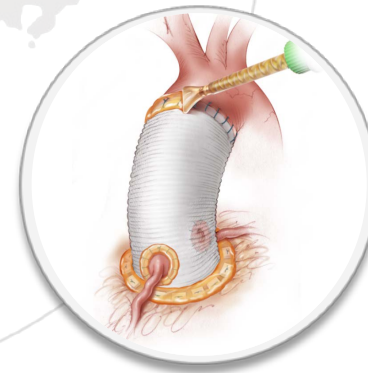
## Direct in Canada, Belgium, Netherlands - 2017



# Global Expansion- Japan BioGlue Indication

## Expanded Indication for BioGlue in Japan

- Current indication only for aortic dissection (5,500 procedures)
- Expanded approval for thoracic aneurysm, Bentall & LVAD (5,500 procedures)
- Doubles existing market from \$5 million to \$10 million
- PMDA approval July 2015
- MHLW reimbursement September 2015

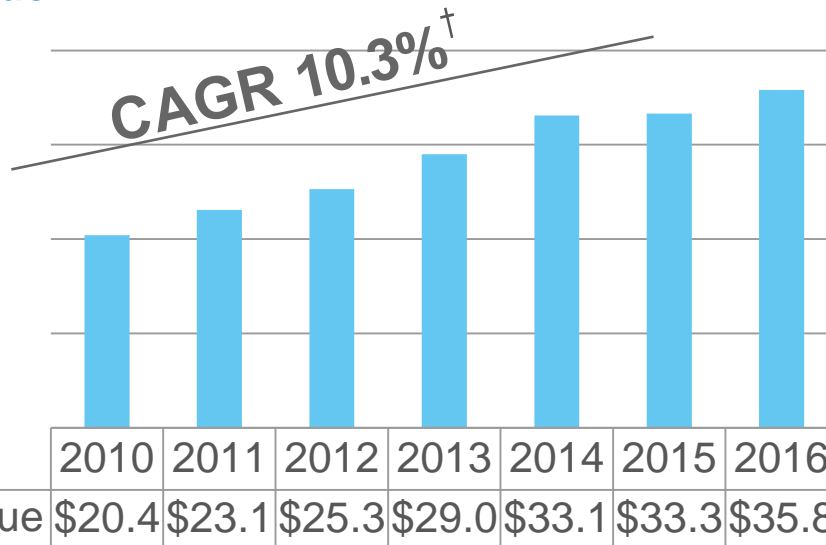


# Global Expansion- BioGlue China

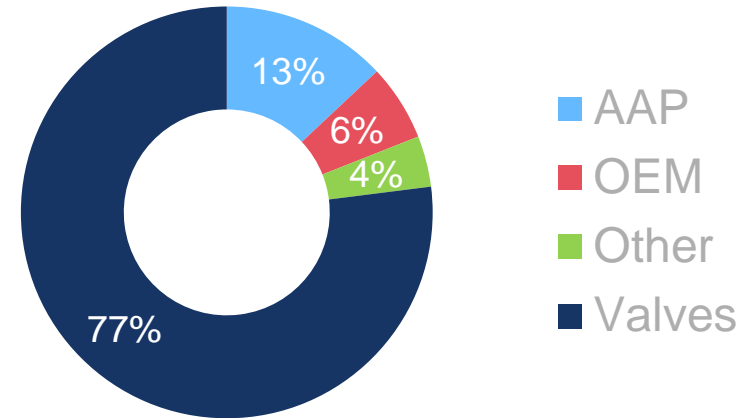
## Clinical Trial and Regulatory Approval for BioGlue in China

- **Significant market opportunity: >40,000 aortic surgeries**
- **Estimated Timeline**
  - **Clinical trial design finalized in 2016**
  - **Standards testing completed, clinical trial approval by CFDA, and Ethics Committee submissions/approvals in 2016**
  - **Enroll trial and collect follow-up in 2017 (3 month follow-up)**
  - **Complete final report and CFDA submission in 2018**
  - **15 months for CFDA approval in 2019**

## Revenue



## Business Mix



## Products



On-X Aortic Valve



On-X Mitral Valve



On-X Ascending Aortic Prosthesis (AAP)



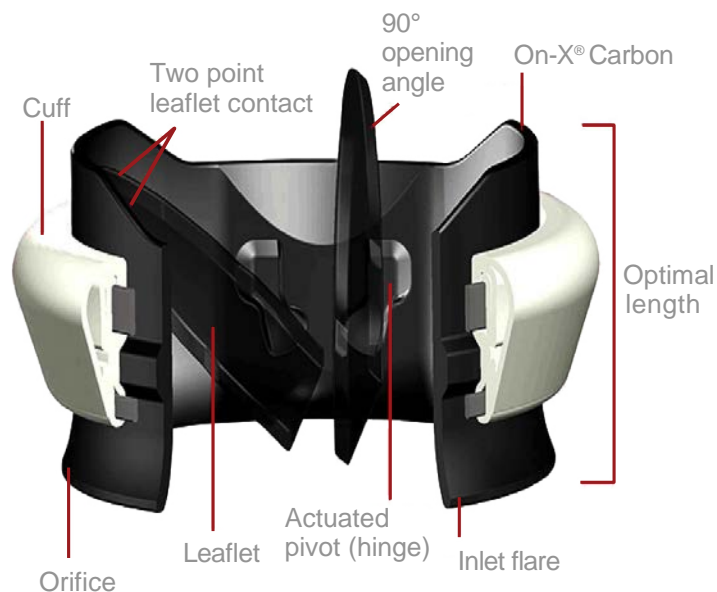
OEM



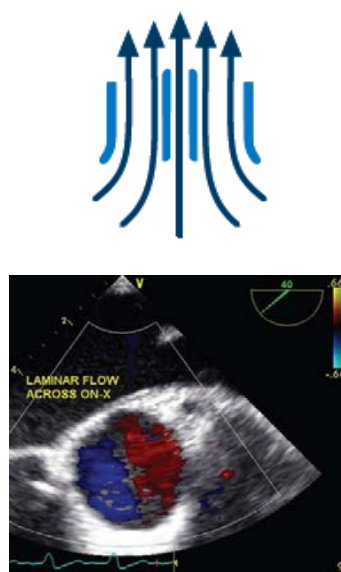
Source: Millennium Research Group

## Aortic Valve Flow Comparison

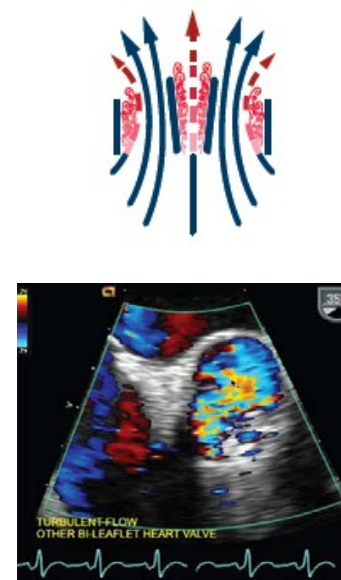
### On-X Valve



### On-X Valve Flow



### Traditional Mechanical Valve Flow



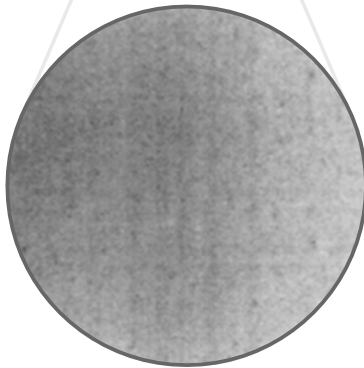
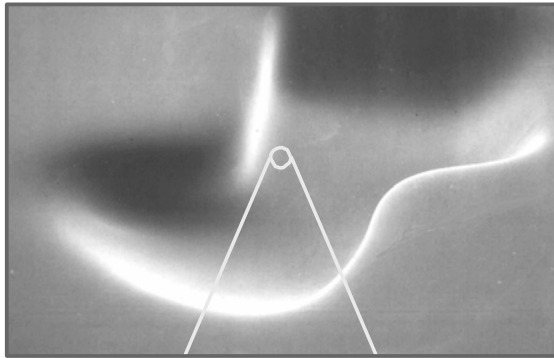
# Best-in-Class Mechanical Valve Technology



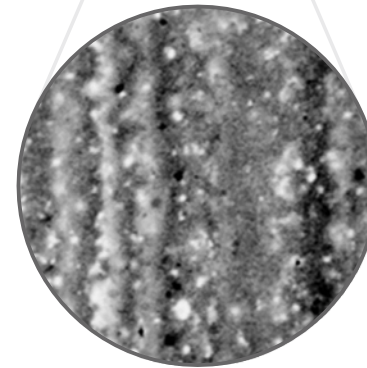
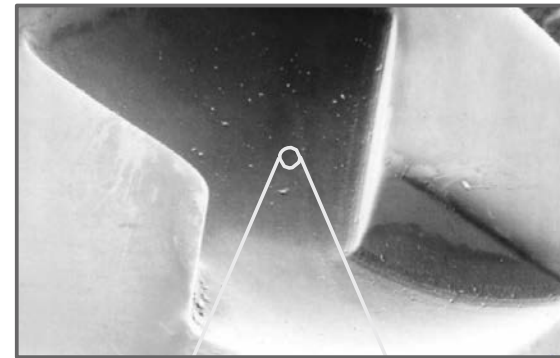
## Microstructure Comparison

### On-X Valve

Silicon-free On-X® carbon



### Market-Leading Competitor



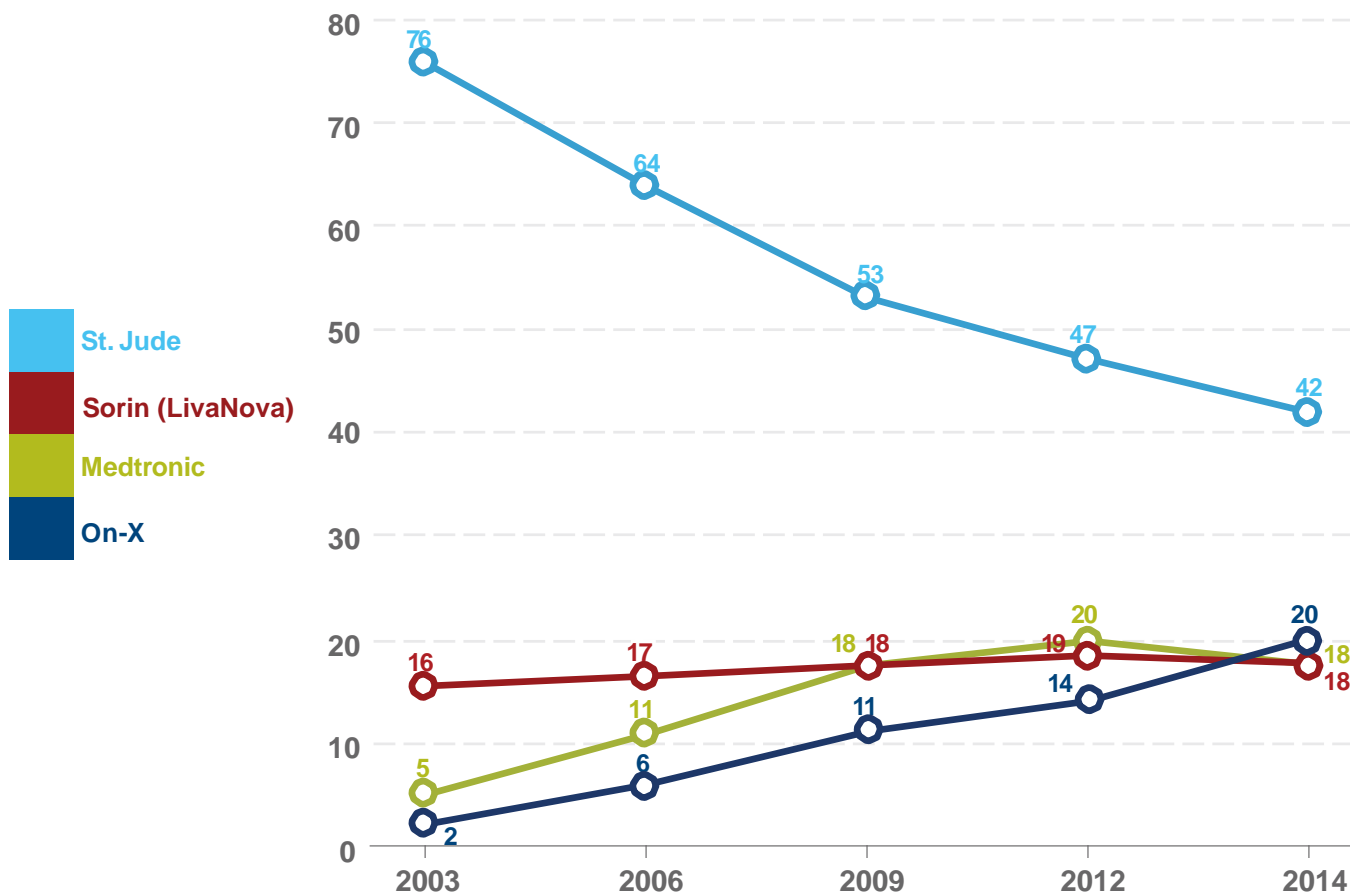


# Steady Growth With Modest Sales Support



## The Power of On-X Technology

### % US Mechanical Valve Market Share

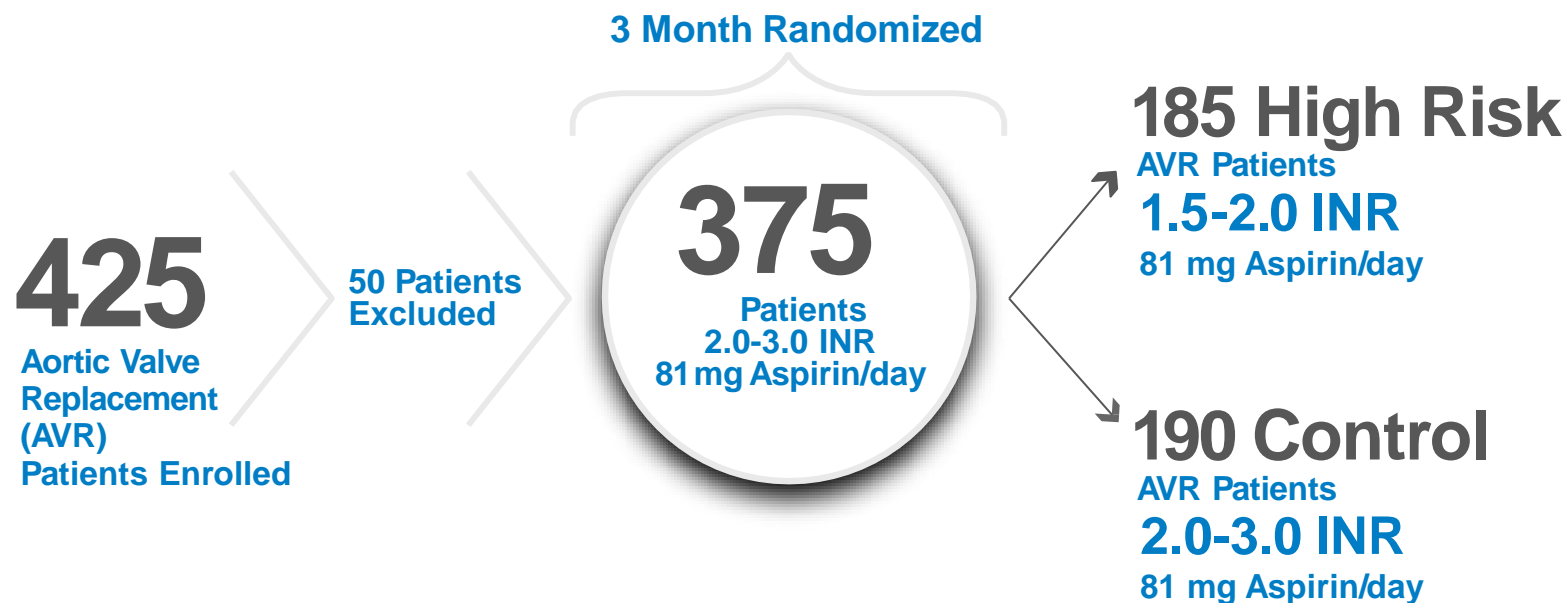


Source: Millennium Research Group

# Significant Recent Developments



PROACT trial results and recent FDA approval of 1.5 to 2.0 INR are catalysts for On-X valve to achieve market leadership



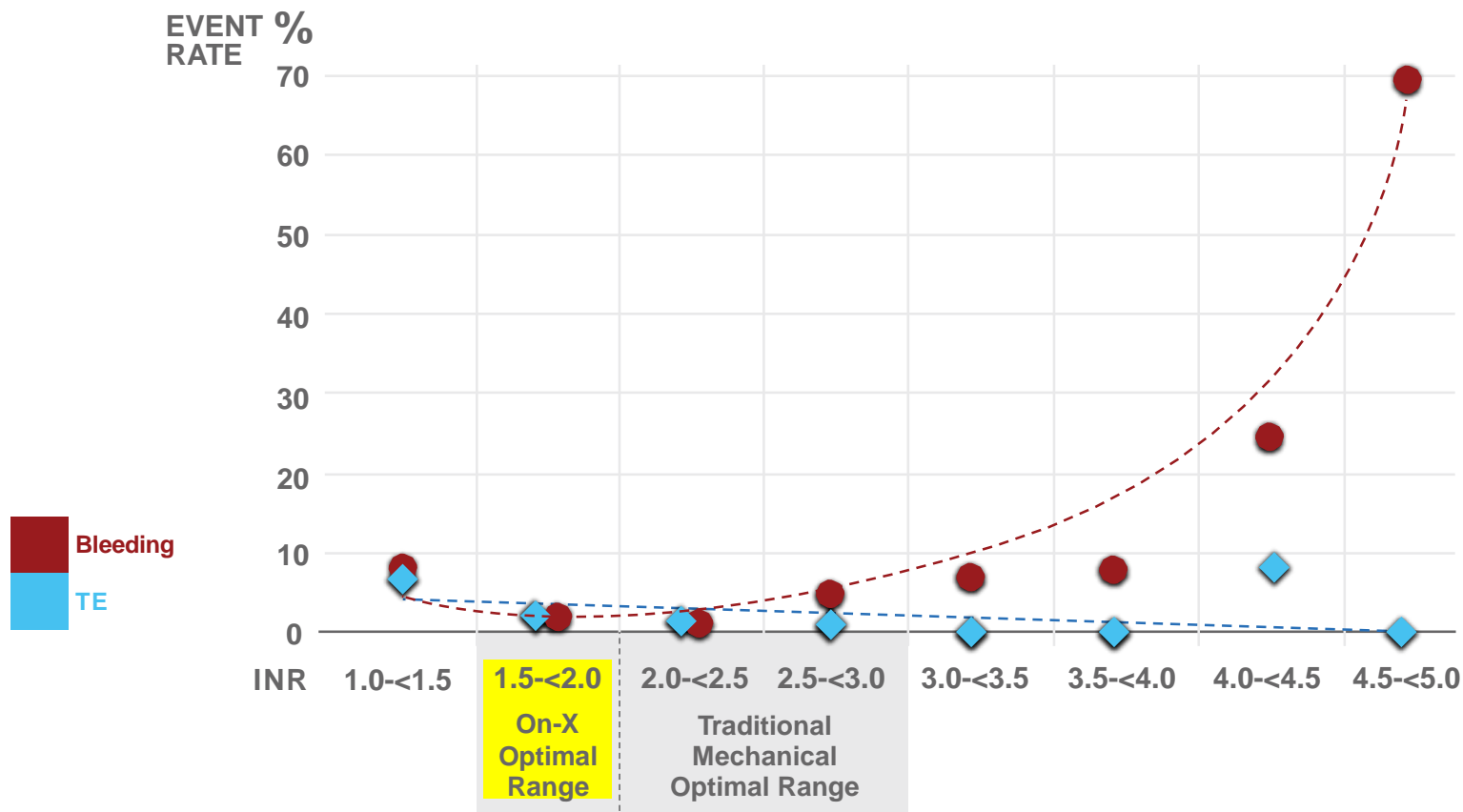
Source: PMA P000037 supplement 30, approval date April 01, 2015



# Clinical Data Supports Future Growth

Data shows an opportunity to switch future patients from tissue

## INR Versus Event Rate



Source: Puskas et al., J Thorac Cardiovasc Surg 2014;147:1202-11

# Clinical Data Supports Future Growth



On-X has the only FDA approved mechanical aortic valve requiring an INR of just 1.5 to 2.0, substantially reducing a patient's bleeding risk — a significant differentiator and distinct competitive advantage

**65%**  
Reduction  
in bleeding

EVENT	CONTROL (ptyr=878.6) (2.0-3.0)		TEST (ptyr=766.2) (1.5-2.0)		RATE RATIO (test/control)	95% CI	P-VALUE
	N	RATE (%/ptyr)	N	RATE (%/ptyr)			
<b>Major Bleed</b>	<b>34</b>	<b>3.87</b>	<b>12</b>	<b>1.57</b>	<b>0.40</b>	<b>0.21-0.78</b>	<b>0.007</b>
Cerebral Bleed	4	0.46	1	0.13	0.29	0.03-2.56	0.264
<b>Minor Bleed</b>	<b>35</b>	<b>3.98</b>	<b>9</b>	<b>1.17</b>	<b>0.29</b>	<b>0.14-0.61</b>	<b>0.001</b>
<b>Total Bleed</b>	<b>69</b>	<b>7.85</b>	<b>21</b>	<b>2.74</b>	<b>0.35</b>	<b>0.21-1.57</b>	<b>&lt;0.001</b>
Ischemic Stroke	7	0.80	6	0.78	0.98	0.33-2.92	0.975
TIA	7	0.80	11	1.44	1.80	0.70-4.65	0.223
Neurologic Event	14	1.59	17	2.22	1.39	0.69-2.82	0.359
Peripheral TE	1	0.11	4	0.52	4.59	0.51-41.04	0.173
Thrombosis	2	0.23	2	0.26	1.15	0.16-8.14	0.891
Major Bleed, TE, Thrombosis (AATS Guideline)	51	5.80	35	4.57	0.79	0.51-1.21	0.275
<b>Primary Endpoint</b>	<b>86</b>	<b>9.79</b>	<b>44</b>	<b>5.74</b>	<b>0.59</b>	<b>0.41-0.84</b>	<b>0.004</b>
Sudden Death	3	0.34	3	0.39	1.15	0.23-5.68	0.867
Valve-related Death	3	0.34	2	0.26	0.76	0.13-4.57	0.769
Total Mortality	16	1.82	12	1.57	0.86	0.41-1.82	0.693

Source: PMA P000037 supplement 30, approval date April 01, 2015

# Experienced Global Direct Sales



Combination will create critical mass in global distribution channels with significant opportunities for cross-selling

## U.S. DIRECT SALES FORCE

2015

2016



17 Cardiac Reps



28 Vascular Reps



17 Cardiac Reps

>50 Reps

## EU DIRECT SALES FORCE

2015

2018



23 Reps



0 Reps

>30 Reps



# Strategic Focus on Aortic Surgery and Mitral Valve Surgery

Combination of CryoLife and On-X creates a highly differentiated product portfolio with a strategic focus on aortic and mitral valve surgery





# Recent Additions to Leadership Team



**PAT MACKIN**, Chairman, President & Chief Executive Officer

*20 + Years Experience*

**Previous Companies:** Medtronic, Genzyme, Deknatel/Snowden-Pencer

**Education:** B.S. United States Military Academy at West Point and M.B.A. Kellogg Graduate School of Management at Northwestern University



**JEAN HOLLOWAY**, Senior Vice President, General Counsel & Corporate Secretary

*30 + Years Experience*

**Previous Companies:** C.R Bard, Medtronic, Boston Scientific, Guidant Corporation

**Education:** J.D./M.B.A. (cum laude) from the University of Chicago, and two undergraduate degrees from Yale University



**JOHN DAVIS**, Senior Vice President, Global Sales & Marketing

*25 + Years Experience*

**Previous Companies:** CorMatrix Cardiovascular, St. Jude, Medtronic

**Education:** Bachelor of Arts, English from Western Carolina University

# Recent Additions to Leadership Team



**BILL MATTHEWS**, Senior Vice President, Operations, Quality and Regulatory

*30 +Years Experience*

**Previous Companies:** BioDevice Solutions, Fresenius Medical Care, Cardinal Health's Viasys Healthcare, Beiersdorf AG

**Education:** Bachelor of Science in Chemistry from St. Peter's University and Business Administration programs from Rutgers University and Fairleigh Dickson University



**JIM MCDERMID**, Chief Human Resources Officer

*30 Years Experience*

**Previous Companies:** Medtronic, Rockwell International, Hudson Bay Company, Cooper Industries and International Paper

**Education:** M.D. in Human Resources Management, McMaster University and a Bachelor's from University of Toronto

# Active Business Development Program

- ✓ Improve clinical outcomes
- ✓ Reduce healthcare costs
- ✓ Physician preference products
- ✓ Higher growth rate than CryoLife
- ✓ Higher margin than CryoLife
- ✓ Competitive advantage in market
- ✓ Synergistic to CryoLife

# Investment Rationale

- **Established Product Portfolio Driving Profitable Growth**
- **On-X Acquisition Accelerates Growth and Margin Expansion**
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Life Restoring Technologies<sup>®</sup>