



## Introduction

April 9<sup>th</sup>

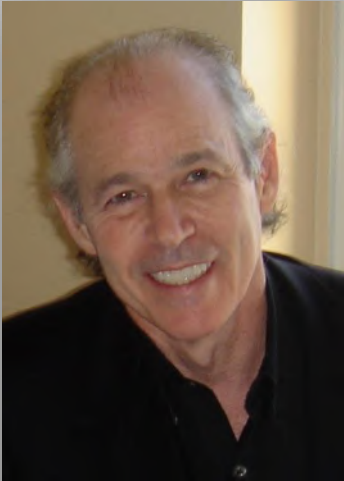
2018



# CONTENTS

- MANAGEMENT
- JARVIK 2000™ IMPLANTS TO DATE
- DESIGN EVOLUTIONS
- COUNTRIES AND CENTERS
- CLINICAL RESULTS
- JARVIK 15MM VAD

Founder and Chairman of the Board;



## **Dr. Robert Jarvik, Chairman and CEO**

- Inventor of the first permanent total artificial heart
- From 1978 to 1987, Dr. Jarvik ran Salt Lake City based, Symbion, a company formed to produce the Jarvik-7 (now Syncardia)
- In 1987, he moved to New York and founded Jarvik Research, where he began work on the Jarvik 2000 Left-Ventricular Assist System
- Dr. Jarvik holds numerous patents for medical device technology
- Received degrees from Syracuse University, New York University, and the University of Utah College of Medicine

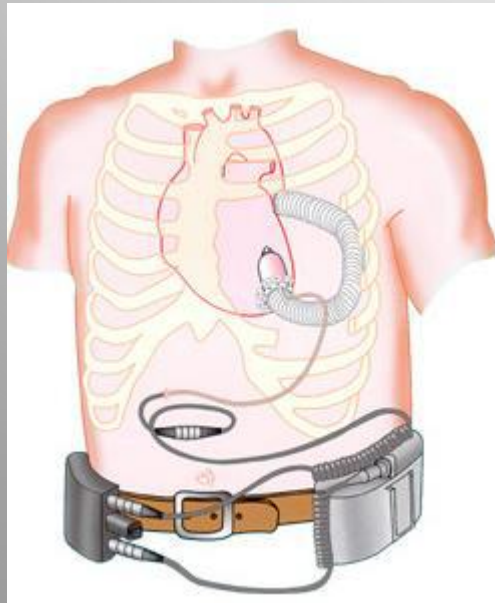
New President bringing higher volume to manufacturing  
and expansion of distribution;



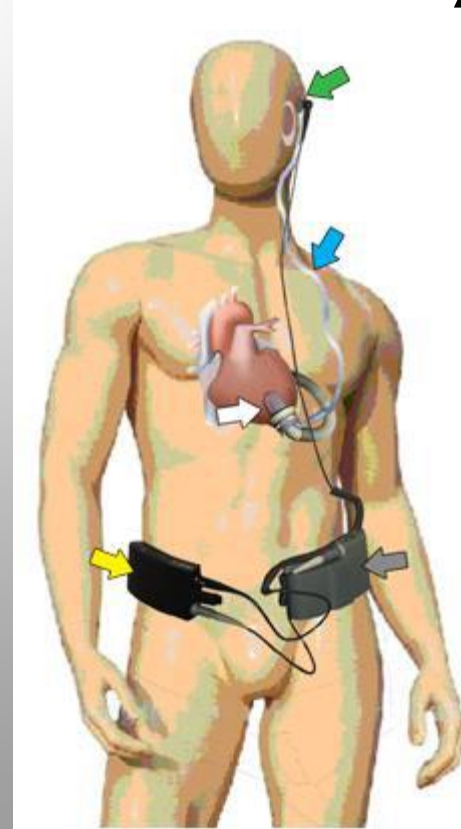
### **Mr. Peter W. J. Hinchliffe, President and COO**

- Joined Jarvik Heart in November 2015
- Over 25 years of medical device development experience
- Holds over 99 issued US medical device patents in many fields
  - General surgery, laparoscopic, endoscopic, interventional radiology and cardiology, orthopedics, oncology, vascular and cardiac surgery
- Over 15 years in senior management positions at various start up, multi-million to billion dollar companies including;
  - US Surgical, Rex Medical, DataScope, ISI, Deep Vein Medical and Maquet/Getinge

# Jarvik 2000™ Ventricular Assist System



Abdominal Driveline\*



Post-Auricular Driveline\*

**Two Product Options Available Today**

# Jarvik 2000 FlowMaker controller and Battery packs.

Day time



Night time



# Jarvik 2000<sup>®</sup> Implant Summary

## Implant Summary\*

- 1036 adult Jarvik 2000<sup>®</sup> patients implanted
- 272 patients transplanted
- Cumulative total pump support experience of more than 1,317 years



## Support Duration\*

<u>Duration</u>	<u>Implants</u>
>9 years	n=1
>8 years	n=2
>7 years	n=8
>6 years	n=17
>5 years	n=28
>4 years	n=51
>3 years	n=104
>2 years	n=213
>1 year	n=373
>6 months	n=535

## Patients on Support\*

Total 185 worldwide.

Croatia=1  
 France=24  
 Hungary=1  
 Italy=53  
 Japan=94  
 Monaco=2  
 Switzerland=1

Florida=2  
 NYP=2  
 Utah=5

# Design Evolution/Milestones

Year	Evolution
2000	Started clinical use in EU
2000	Post Auricular Driveline
2003	Intermittent Low Speed Control (ILS) in EU
2005	Titanium Microsphere coating
2005	CE mark for launch in EU
2010	Cone Bearings
2013	PMDA Approval in Japan
2016	15mm receives IDE approval to begin FDA trial
2017	15mm Pediatric Clinical Trial Starts



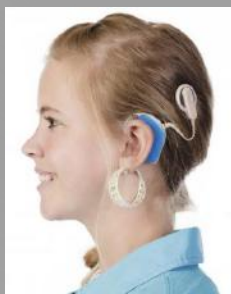
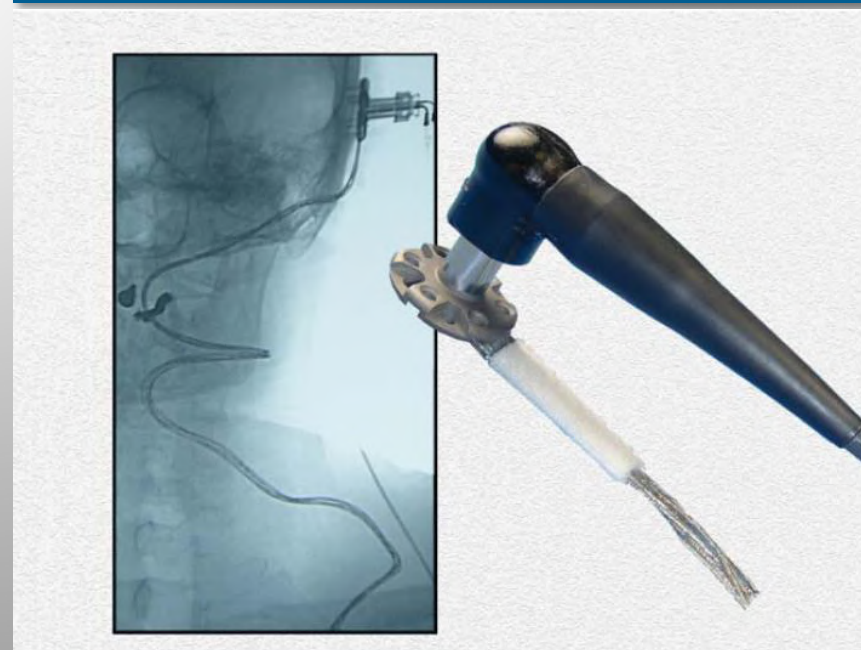
Year 2000

# Unique Post-Auricular Connector

Cochlear Implant Pedestal



Jarvik Heart Post-Auricular Connector



## Unique Jarvik Post-Auricular Connector

Jarvik 2000 post-auricular driveline option is the most successful long-term power access in terms of patient safety and quality of life

- Has remained **infection free for >9 years**
- No dressings required = **major QOL benefit**
- No dressings required = major **cost advantage**
- Permits bathing, showering and even swimming
- External cable completely replaceable if damaged
- Improved “body image” and “freedom” compared to abdominal driveline

## Jarvik 2000

*Post-Auricular Connector**Abdominal Connector*

Quality of Life...

Only Jarvik 2000 VAD patients can truly bathe



# Enjoy a better Quality of Life

**Post-Auricular Driveline enables complete immersion**



## Quality of Life for Destination Therapy patients

**Muscular dystrophy patient unable to walk but free to swim**



## Post-Auricular Freedom

Living life as close to normal as possible



# Jarvik 2000 experiences

## Very Few Serious Driveline Infections

Jarvik Abdominal driveline; 496 implanted, support days = over 160,861

Jarvik Post-Auricular driveline; 516 implanted, support days = over 290,093

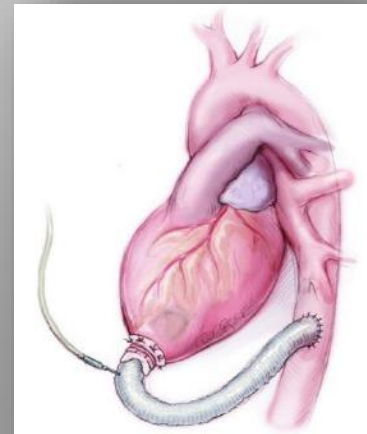
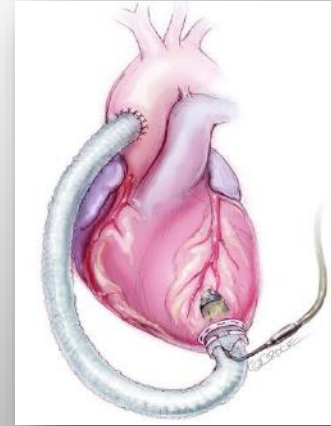
	No. of Patients	% of Patients	No. of Events	Events/365 Days
Abdominal	38	7.7%	43	0.098
Post-Auricular	7	1.4%	7	0.009

Competitive products with abdominal drivelines consistently report over 10% infection rates, with some reports over 50%.

*What is your experience?*

## 2003 Intermittent Low Speed (ILS)

- Intermittent Low Speed (ILS) control mode reduces the pump speed to 7,000 rpm for eight seconds each minute
- This is designed to exercise the ventricle and aortic valve maintaining a fully functional aortic valve
- ILS is also designed to wash the aortic valve and aortic root every minute enabling descending aortic outflow anastomosis
- Because of ILS the Jarvik Heart is designed to enable many surgical approaches

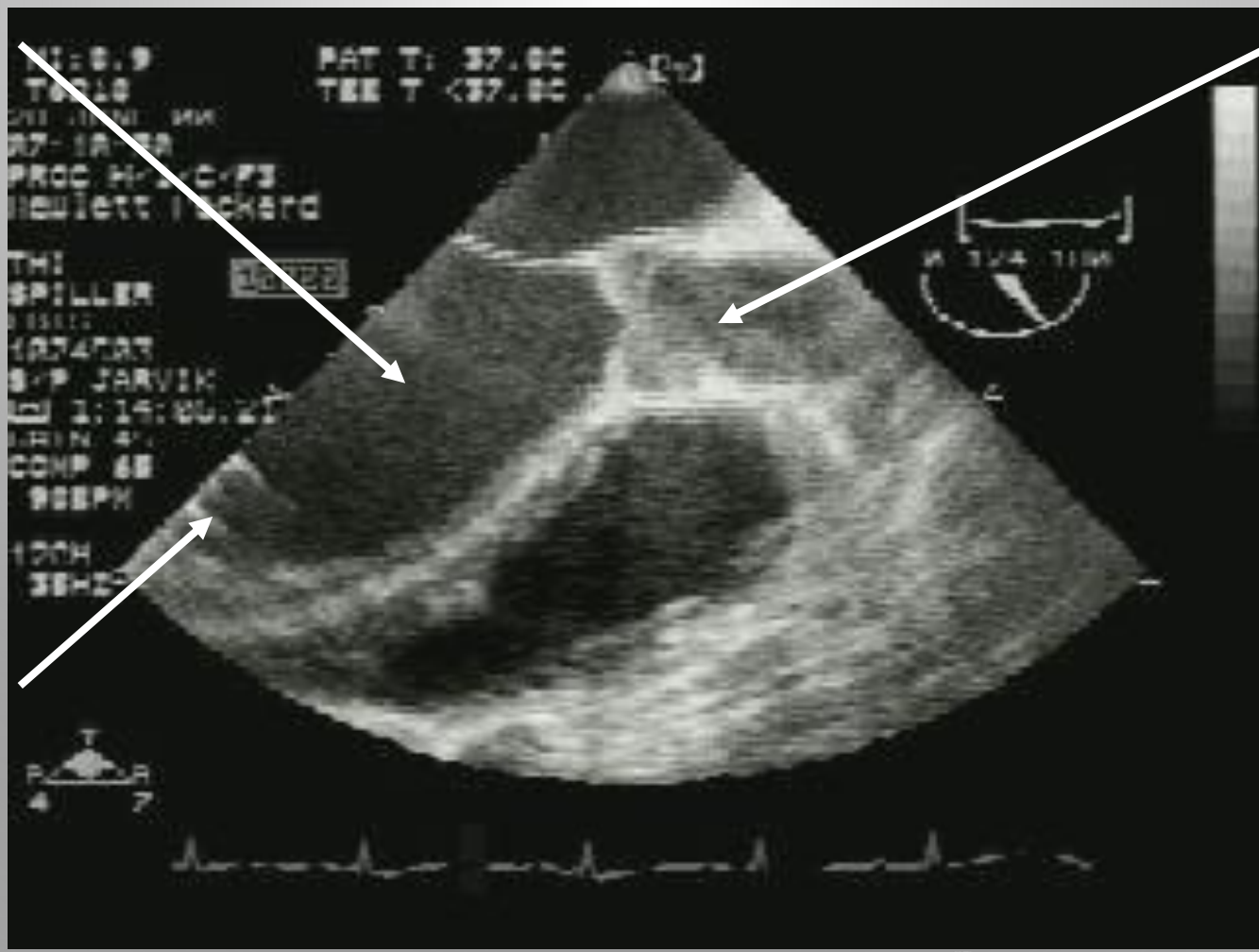




# 2003 Intermittent Low Speed (ILS)

Left ventricle

Aortic root



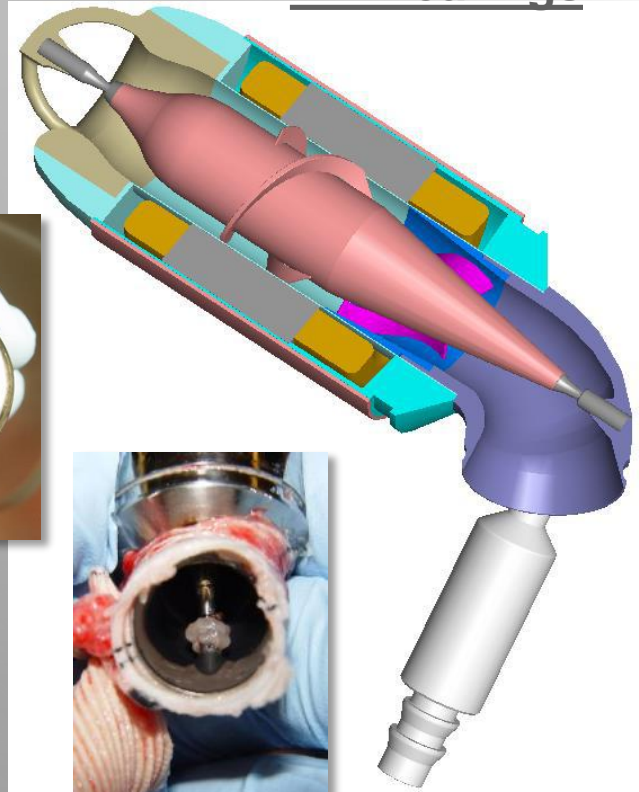
Jarvik 2000

Intermittent Low Speed (ILS) control mode reduces the speed to 7,000 rpm for eight seconds each minute to allow wash out of the aortic valve and root

1999-----→2010-----→Today

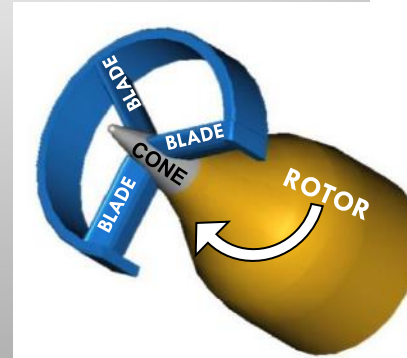
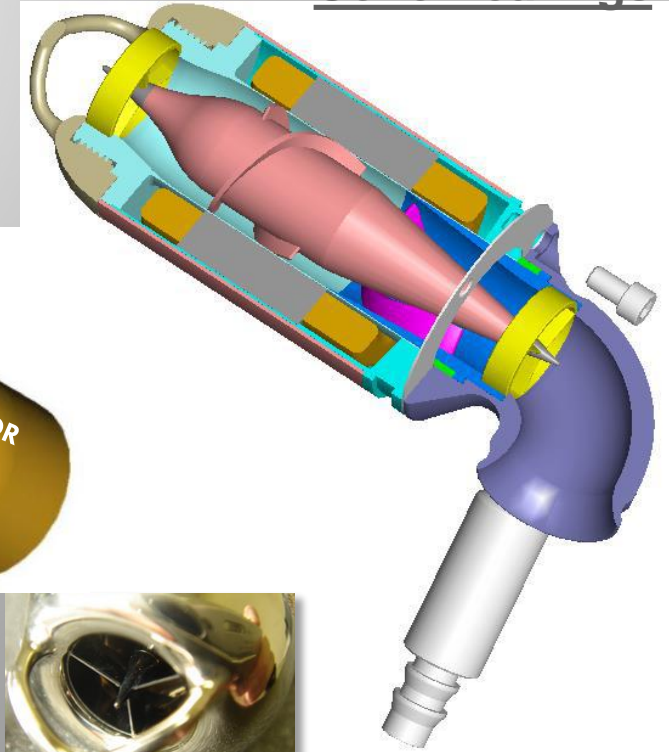
# Pin and Cone Bearing Comparison

## Pin Bearings



- 7.5 years Explant
- 40 billion revolutions
- ~5 microns surface wear

## Cone Bearings



- 3 years Explant
- 14 billion revolutions
- No measurable surface wear

#Pin Bearings Pumps Implanted

= 418

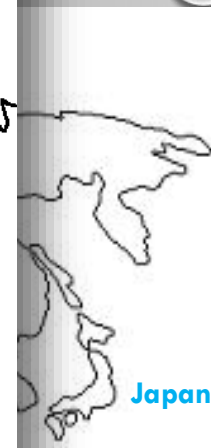
#Cone Bearings Pumps Implanted\* = over 590

\* As of October 19, 2017

2016



# Jarvik 2000 now available in over 30 countries



1	Argentina
2	Belarus
3	Belgium
4	Canada
5	Chile
6	China
7	Colombia
8	Croatia*
9	Czech Republic
10	Denmark
11	Estonia
12	Finland
13	France
14	Germany
15	Greece
16	Hungary
17	Iceland
18	India
19	Ireland
20	Italy

21	Japan
22	Kazakhstan
23	Kuwait
24	Latvia
25	Lithuania
26	Monaco
27	Norway
28	Portugal
29	Saudi Arabia
30	Serbia
31	Slovenia*
32	Spain
33	Sweden
34	Switzerland
35	UAE
36	UK
37	Ukraine
38	US

## Countries & Centers Today

United States

IDE Clinical Trial (DT)

around 10 Centers

Europe CE Mark for BTT & DT

20 Centers in Italy

around 11 Centers in France

Japan Shonin BTT

around 19 Centers in Japan

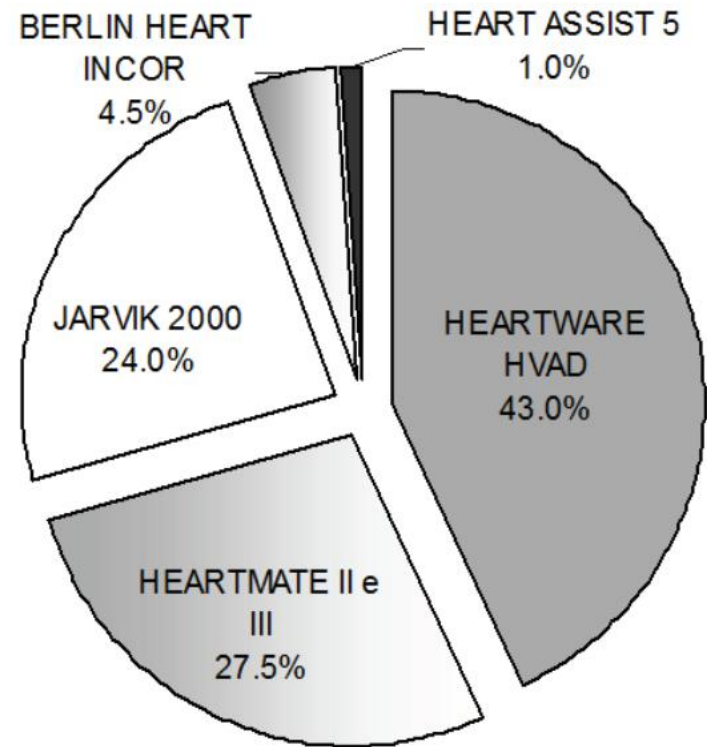
Country	Center	Number Patients Implanted
<b>France</b>		
	Bordeaux	15
	Caen	18
	Creteil	3
	Grenoble	2
	La Pitie	52
	Lyon	15
	Marie Lannelongue	21
	Nantes	1
	Rennes	15
	Tours	8
	Nancy	5
<b>Greece</b>		
	St. Luc Thessaloniki	17
	Univ. of Thessaloniki	4
<b>Monaco</b>		
	Monaco	15
<b>TOTALS</b>		<b>191</b>

Country	Center	Number Patients Implanted
Italy		
	Bambino Gesu	16
	Bologna	4
	Catanzaro	4
	Chieti	22
	Florence	2
	Gemelli	3
	Legnano	2
	Mantova	2
	HSR Milan	3
	Centro Cardiologico Monzino Milan	18
	Monza	1
	Padova	61
	Pavia	3
	Perugia	5
	Rome	2
	San Filippo Neri	1
	Siena	32
	Torino	4
	Udine	36
	Vicenza	1
<b>TOTALS</b>		<b>222</b>



## Dispositivi impiantati (2010-2015)

DEVICE TYPE	#
HEARTWARE HVAD	219
HEARTMATE II	139
HEARTMATE III	1
JARVIK 2000	122
BERLIN HEART INCOR	23
HEART ASSIST 5	5
<b>ADULT C.F. LVAD (Total)</b>	<b>509</b>
TAH	17





Country	Center	Number Patients Implanted
Japan		
	Tokyo University	39
	Osaka Univ. Hospital	43
	Tohoku Univ. Hospital	12
	Chiba Univ. Hospital	16
	National Cerebral and Cardiovascular Center	13
	Tokyo Metropolitan Geriatric Hospital	4
	Saitama Medical Univ.	4
	Kyushu Univ. Hospital	7
	Tokyo Women's Medical Univ. Hospital	4
	Tokyo Medical and Dental Univ. Hospital	2
	Tottori Univ. Hospital	1
	Shinshu Univ. Hospital	2
	U of the Ryukyu Hospital	1
	Hokkaido Univ. Hospital	1
	Dokkyo Medical Univ.	3
	Ehime Univ. Hospital	2
	Okinawa Nanbu Medical Center	1
	Gunma Cardiovascular Center	2
	Mitsui	1
	Kobe	1
	Tsukuba	1
<b>TOTALS</b>		<b>160</b>

35% to 40%  
Market Share  
2015-2017

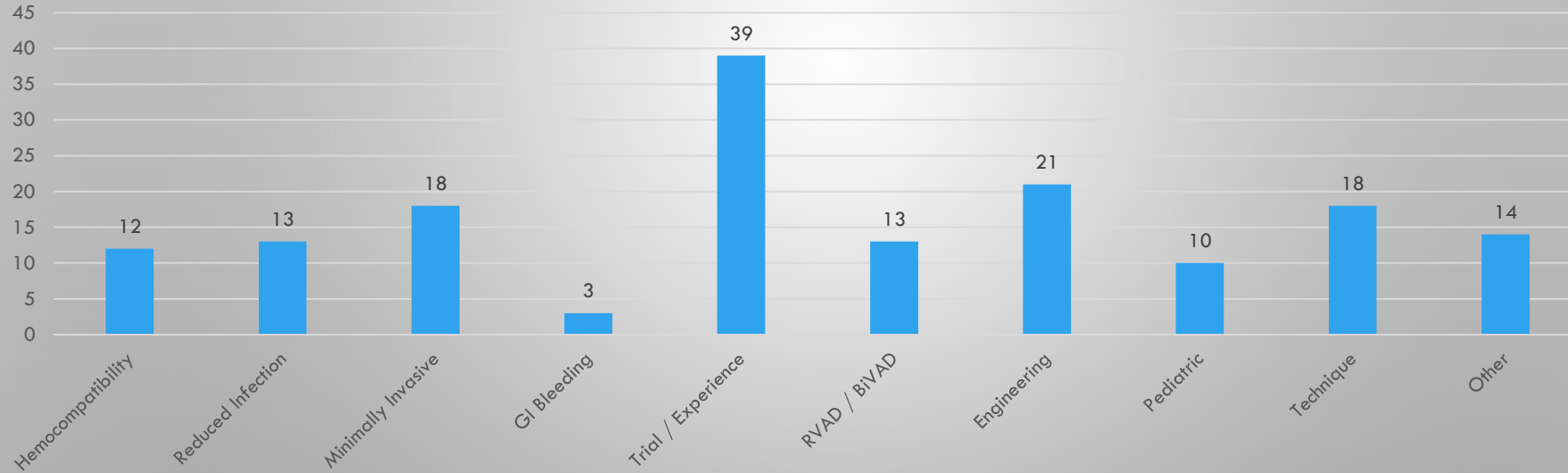
\* As of October 19, 2017 including implants in Japanese trial prior to PMDA approval

Country	Center	Number Patients Implanted
Germany		
	Aachen	1
	Bad Rothenfelde	5
	Berlin	10
	Freiburg	11
	Munich	43
<b>TOTALS</b>		<b>70</b>

## Clinical Results

# Clinical Publication Overview

Publications by Subject



Category	Hemocompatibility	Reduced Infection	Minimally Invasive	GI Bleeding	Trial / Experience	RVAD / BiVAD	Engineering	Pediatric	Technique	Other	Total
<b>Number of Papers</b>	12	13	18	3	39	13	21	10	18	14	161
<b>Publication number</b>	43, 65, 79, 84, 96, 98, 100, 108, 113, 117, 129, 133	4, 15, 24, 46, 50, 82, 97, 106, 111, 120, 142, 148, 159	6, 20, 21, 22, 53, 54, 67, 69, 70, 72, 103, 119, 127, 130, 135, 141, 144, 145	41, 58, 91	2, 8, 9, 10, 11, 13, 16, 17, 18, 19, 23, 28, 29, 30, 31, 32, 35, 38, 45, 52, 57, 59, 60, 61, 73, 74, 75, 77, 78, 86, 88, 124, 146, 147, 149, 153, 154, 157, a	27, 37, 39, 51, 64, 95, 99, 114, 125, 126, 136, 137, 143	1, 5, 7, 25, 26, 55, 56, 62, 68, 76, 80, 81, 83, 85, 89, 90, 121, 122, 139, 140, 151	3, 49, 66, 110, 112, 115, 132, 138, 152, 158	12, 14, 63, 71, 87, 92, 93, 94, 101, 102, 104, 105, 107, 109, 116, 118, 123, 128,	33, 34, 36, 40, 42, 44, 47, 48, 131, 134, 150, 155, 156, b.	

PDF

117. Tarzia V. et al. "Different impact on the coagulation system of two continuous flow LVADs: axial versus centrifugal flow." *J Heart Lung Transplant*. 2013 Apr;32(4):S177.

**Subject: Hemocompatibility**

#### Abstract

Antithrombotic therapy is essential in LVAD recipients and must be carefully titrated in each patient. Different devices might influence the coagulation system differently. An awareness of this may allow early planning of the most appropriate antithrombotic approach according to LVAD type. We studied the impact of two different continuous flow LVADs on the coagulation system: Jarvik 2000, an axial flow pump, versus HeartWare HVAD, a magnetically levitating centrifugal pump.

**Conclusions:** The two pumps have markedly different effects on hemostasis. The HeartWare causes hyperactivation of the coagulation system compared to the Jarvik. Accordingly, HeartWare patients usually need both anticoagulant and antiplatelet drugs, while Jarvik patients are usually managed only with anticoagulation.

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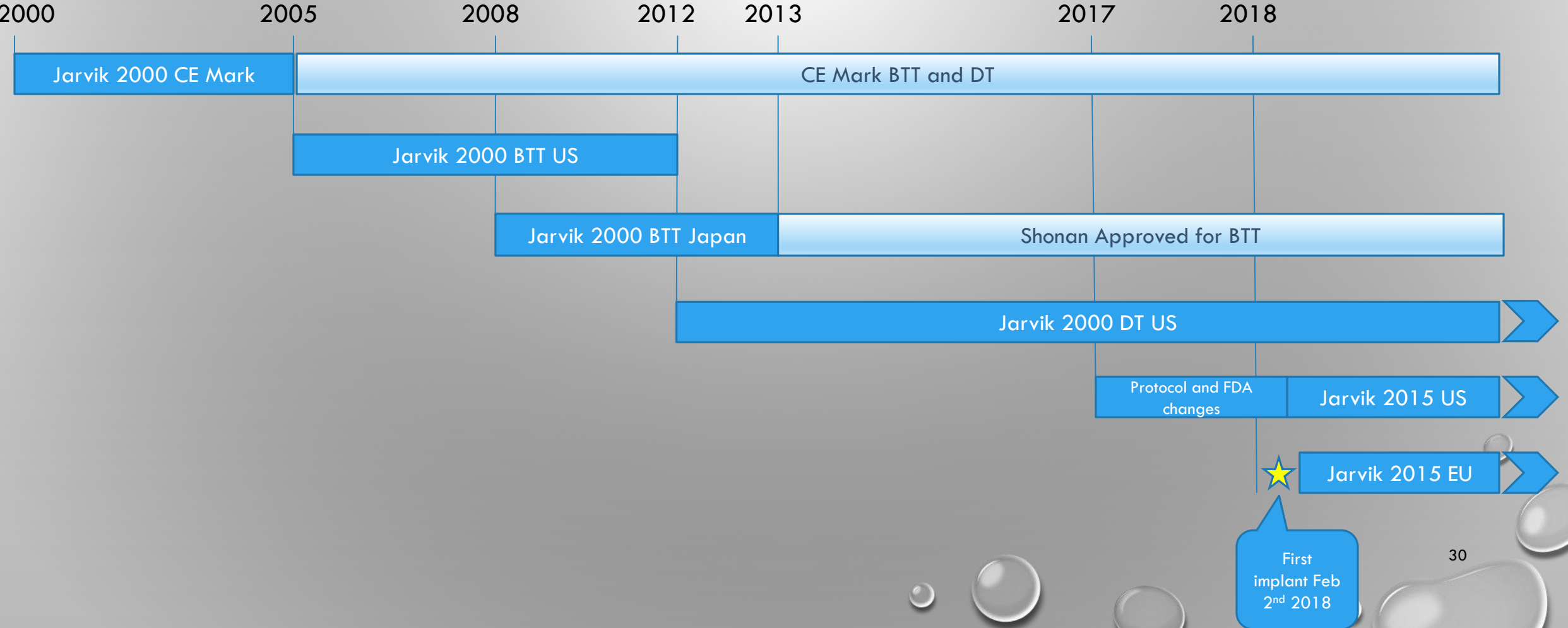
#### Different Impact on the Coagulation System of Two Continuous Flow LVADs: Axial Versus Centrifugal Flow

V. Tarzia,<sup>1</sup> F. Vasques,<sup>1</sup> G. Bortolussi,<sup>1</sup> J. Bejko,<sup>1</sup> M. Gallo,<sup>1</sup> M. Carrozzini,<sup>1</sup> M. Comisso,<sup>1</sup> E. Buratto,<sup>1</sup> M. De Franceschi,<sup>1</sup> E. Campello,<sup>2</sup> L. Spiezia,<sup>2</sup> P. Simioni,<sup>2</sup> T. Bottio,<sup>1</sup> G. Gerosa.<sup>1</sup>

<sup>1</sup>Department of Cardiac Thoracic and Vascular Sciences - Cardiac Surgery, University Hospital of Padua, Padua, Italy; <sup>2</sup>Department of Cardiac, Thoracic and Vascular Sciences - Second Chair of Internal Medicine, University Hospital of Padua, Padua, Italy.

**Conclusions:** The two pumps have markedly different effects on hemostasis. The HeartWare causes hyperactivation of the coagulation system compared to the Jarvik. Accordingly, HeartWare patients usually need both anticoagulant and antiplatelet drugs, while Jarvik patients are usually managed only with anticoagulation.

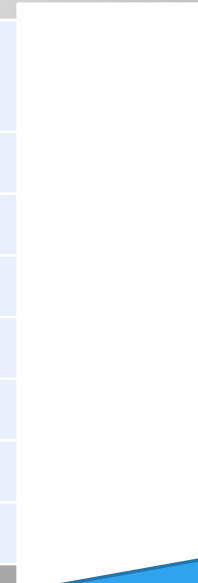
# Clinical Trial Timeline



# Jarvik 2000 US BTT Clinical Trial Data Analysis

Patient conditions relative to newer trials?

	Heartware	HM2	HM3
Intermacs Score	n=140	n=142	n=152
'1	5%	3%	1%
'2	28%	31%	33%
'3	44%	49%	50%
'4	12%	16%	15%
'5	5%	1.4	1%
'6 or 7	6%	0	0%

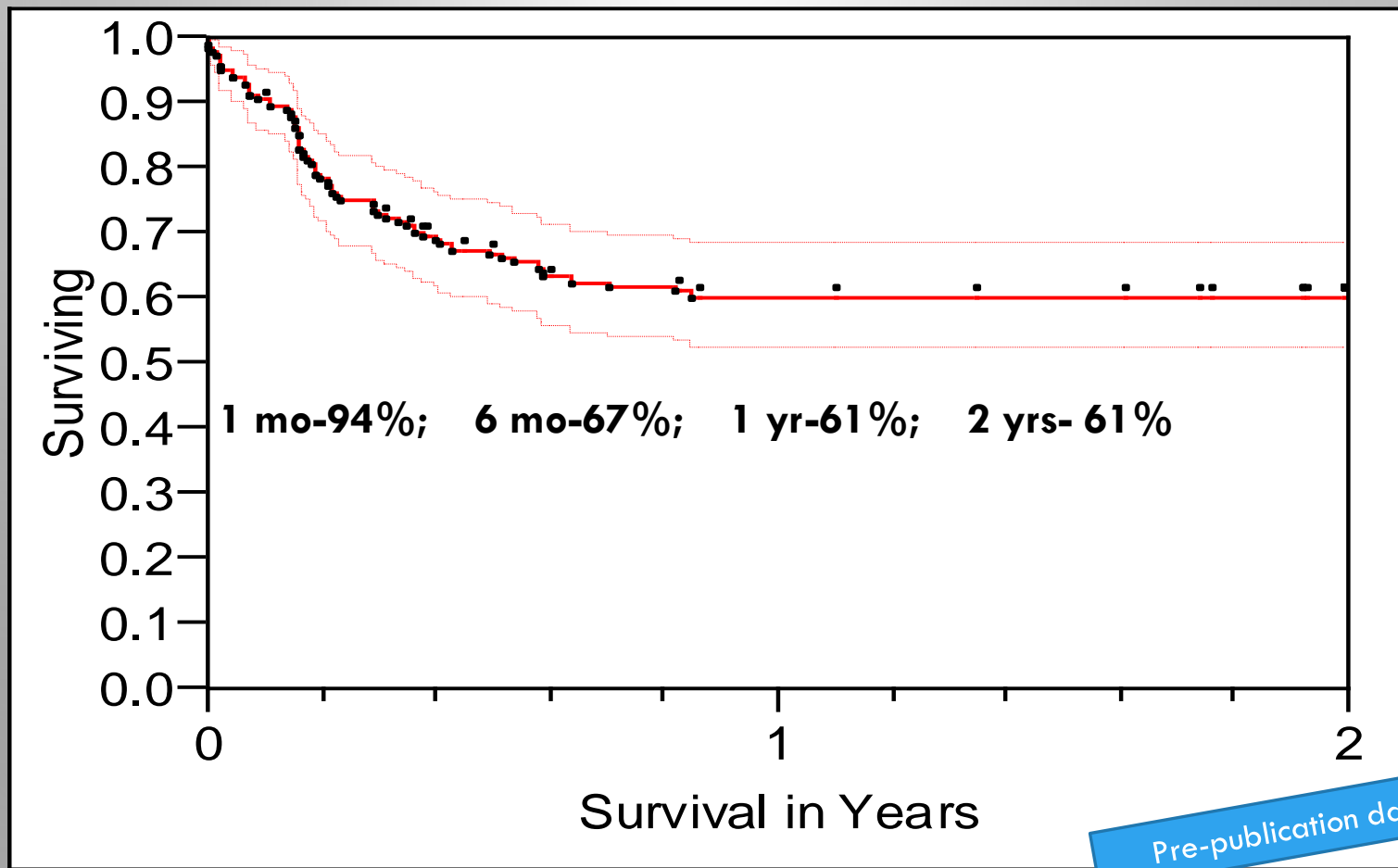


Much sicker patients

Pre-publication data

## US BTT Clinical Trial Data

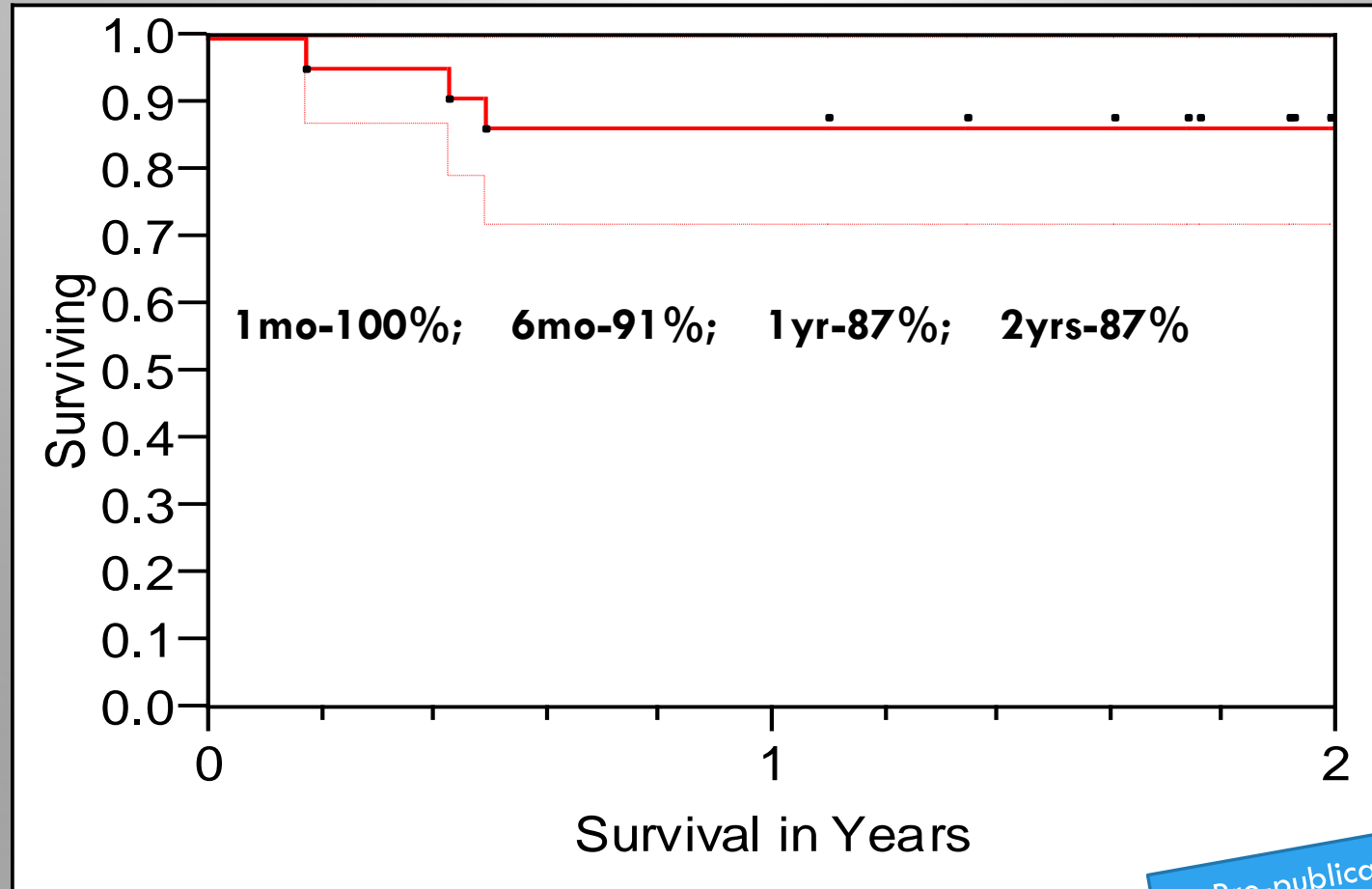
**Kaplan-Meier Survival of Jarvik 2000<sup>®</sup> BTT  
Cone & Pin Bearing Patients (n=150) with 95% Confidence Intervals**



Pre-publication data



## US BTT Clinical Trial Data

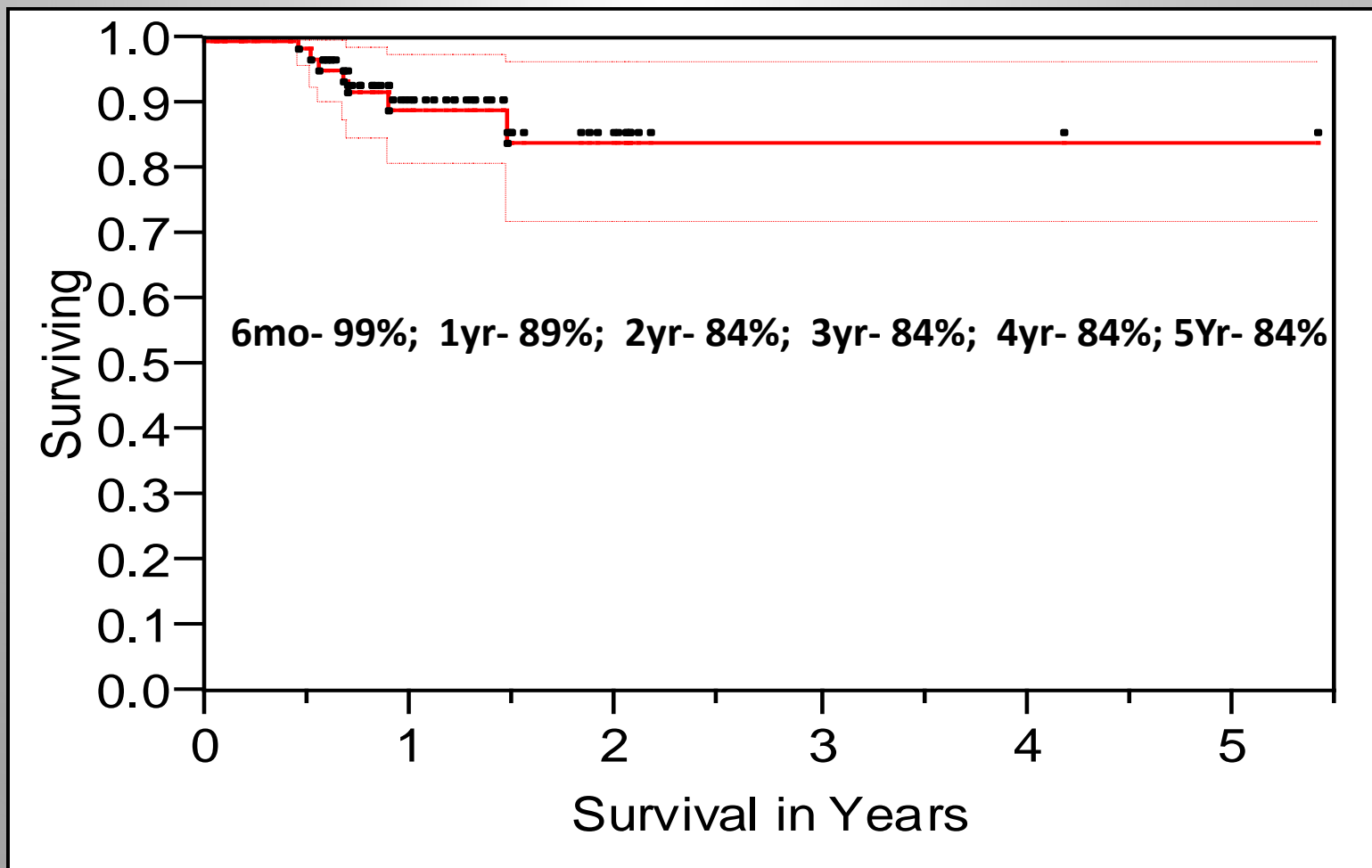
Kaplan-Meier Survival of Jarvik 2000™ BTT  
Cone Bearing Patients (n=22) with 95% Confidence Intervals

Pre-publication data



# All Japanese Implants\*

All Cone Bearing Patients in Japan, (n=82)  
 (Beginning in 2010 when cone bearings first released)



\* As of April 2016

## All Italian Cone Bearing Implants\*

Italian Patients Jarvik 2000 Cone Bearings		Total Group (N = 181)	Adult Group (N = 167)
Age	yr	57.6±15.2	61.2±9.2
Male gender	no. (%)	155 (86)	143 (86)
Body-surface area	m <sup>2</sup>	1.8±0.2	1.9±0.2
INTERMACS profile	no. (%)		
	1	36 (20)	29 (17)
	2	28 (15)	28 (17)
	3	54 (30)	47 (28)
	4	57 (31)	57 (34)
	5	6 (3)	6 (4)
Ischemic cause of HF	no. (%)	85 (47)	85 (51)
Indication DT & BTC	no. (%)	142 (78)	135 (81)

← 17-20% INTERMACS 1

← 78-81% DT patients

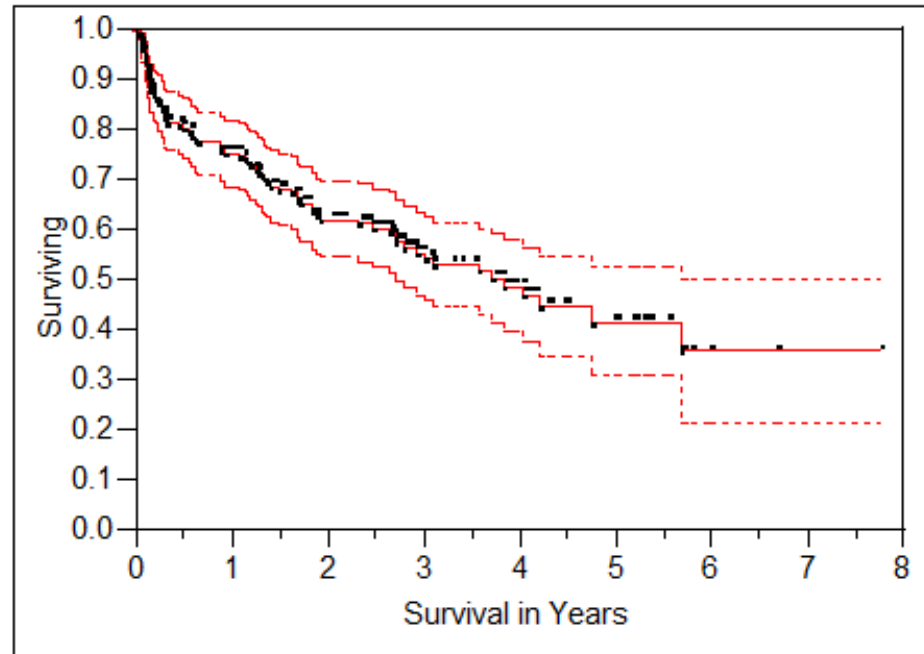
# All Italian cone bearing Implants\*

**Kaplan-Meier Curve for Italian patients with  
Jarvik 2000 Cone Bearing VAD with > 15 days survival  
n=171**

**Survival at 6 months is 80%, 1 year is 75%, and 2 years is 62%.**

***Currently longest ongoing Italian patient is 2844 days (7.8 years)***

***Longest Italian patient survival was 2906 days (nearly 8 years)***





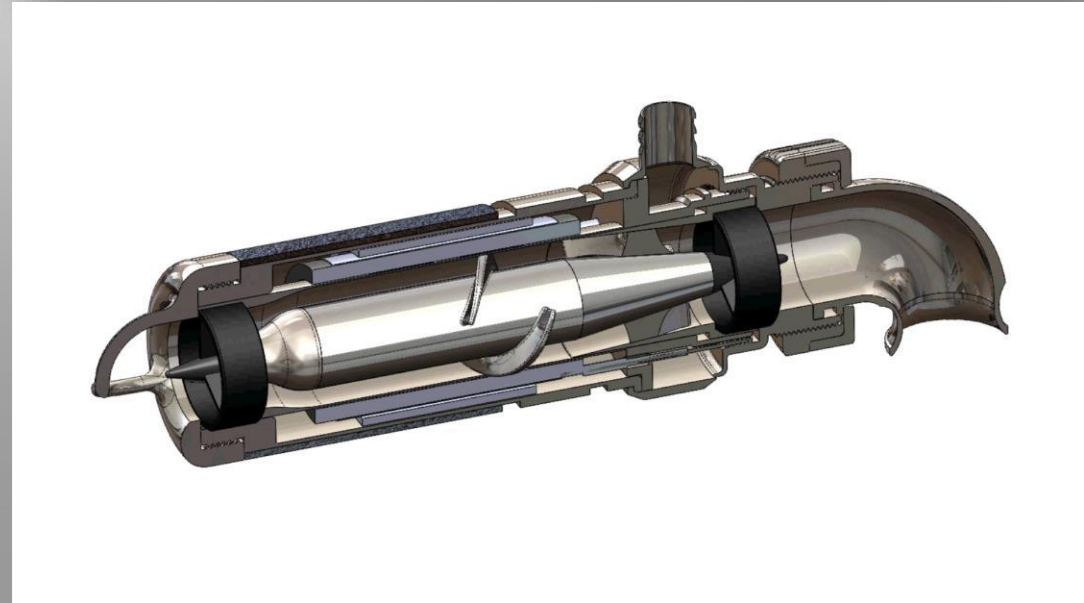
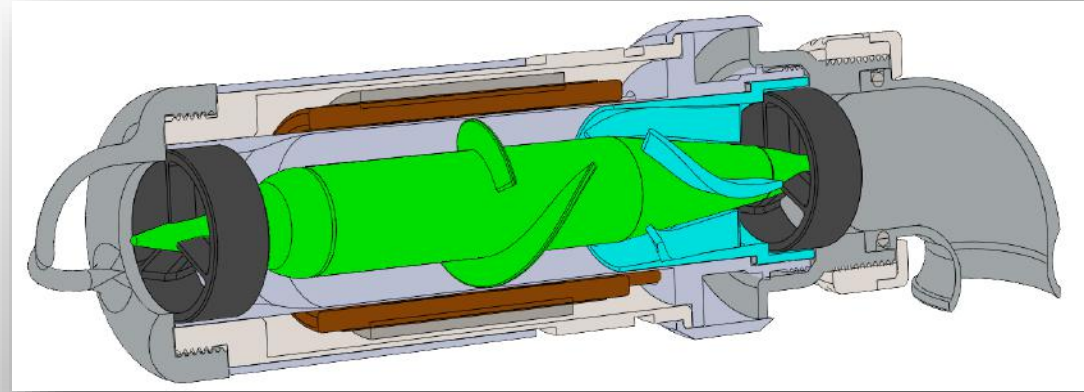
# JARVIK 15MM

## IN US CLINICAL TRIAL 2017

(1-4LPM VAD)

# DEVICE OVERVIEW

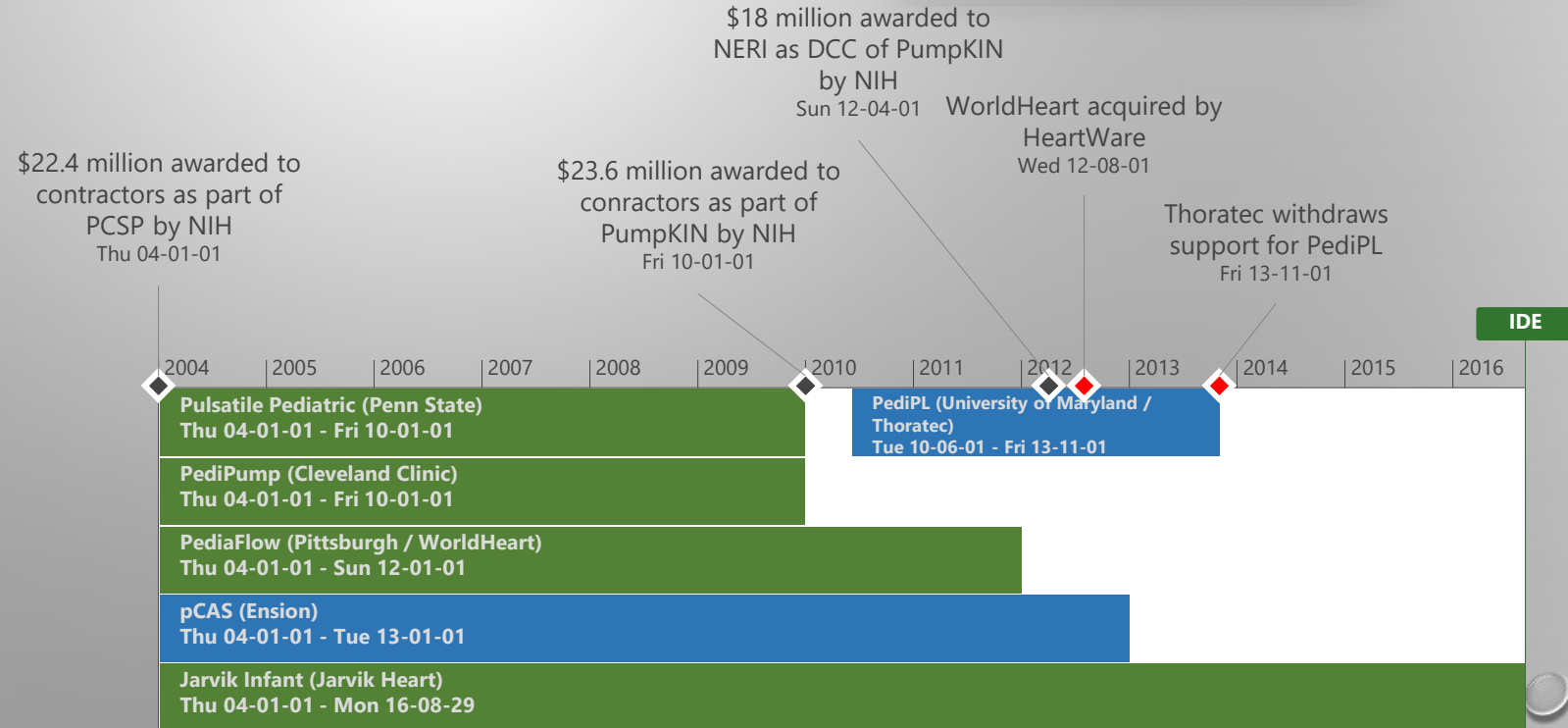
THE JARVIK 2015 IS AN AXIAL-FLOW VENTRICULAR ASSIST DEVICE INTENDED, INITIALLY, FOR PEDIATRIC USE. IT MAKES USE OF PROVEN DESIGN FEATURES SUCH AS THE JARVIK CONE BEARINGS OF THE JARVIK 2000 AND USES THE SAME FAMILY OF EXTERNAL BATTERY AND CONTROLLER COMPONENTS.



# ABOUT THE PUMPKIN PROGRAM

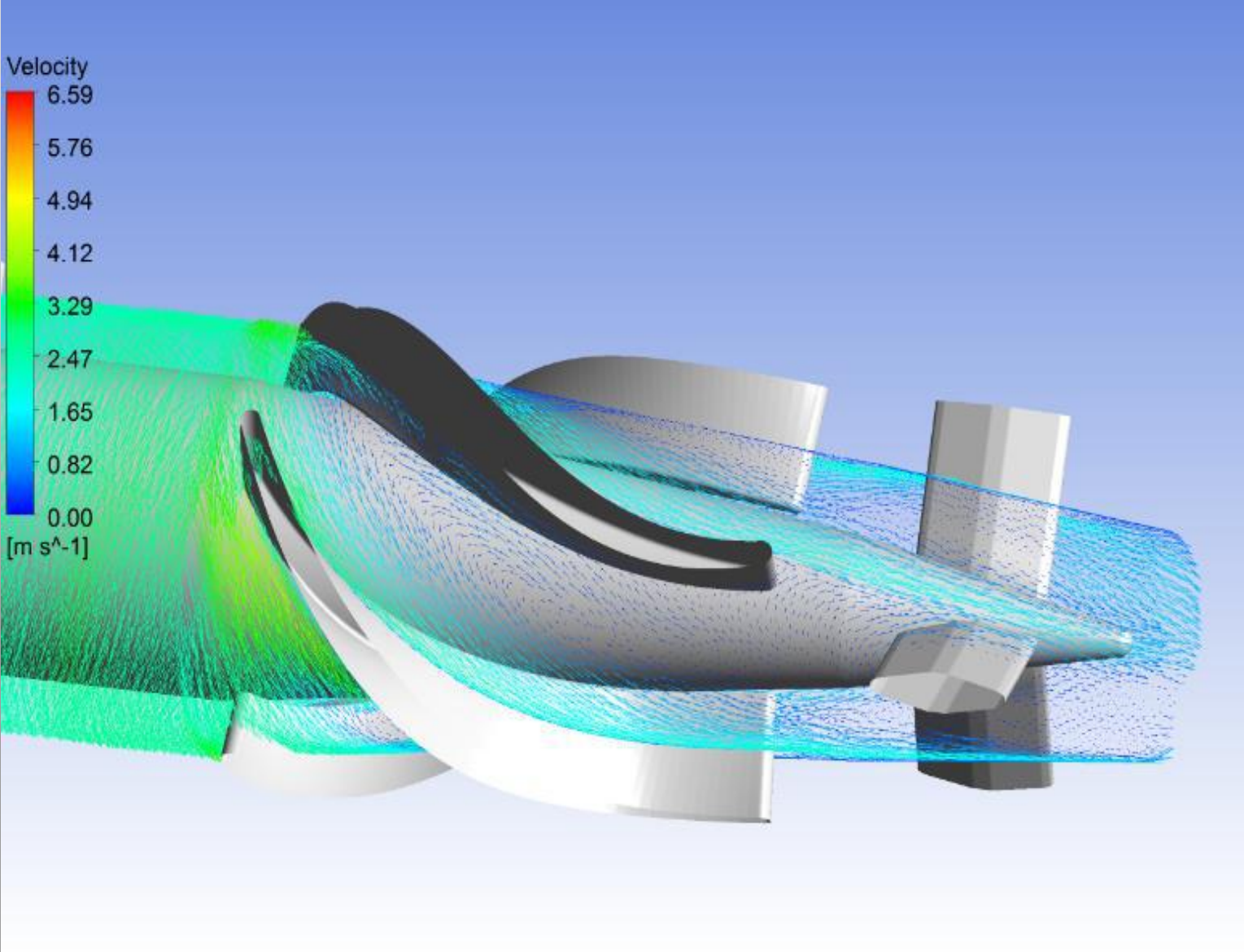
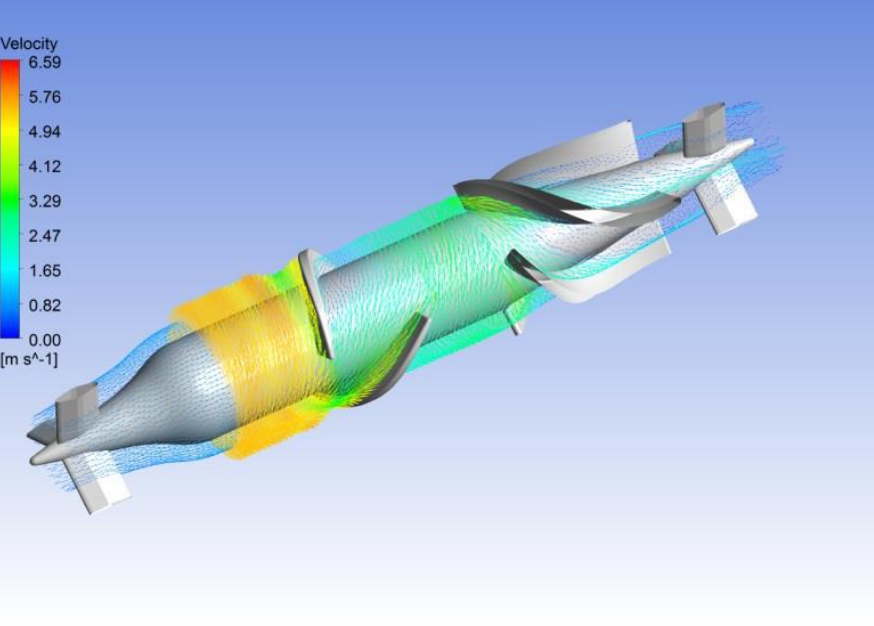


- THE PUMPKIN PROGRAM, UNDER THE LEADERSHIP OF DR. TIM BALDWIN, HAS BEEN FUNDED BY THE NATIONAL INSTITUTE OF HEALTH TO DEVELOP MCS DEVICES FOR PEDIATRIC PATIENTS
- OVER \$64 MILLION HAS BEEN AWARDED TO SIX DIFFERENT INSTITUTIONS TO FUND RESEARCH AND DEVELOPMENT OF PEDIATRIC-SPECIFIC ECMO AND IMPLANTABLE VADS
- AFTER MORE THAN 12 YEARS, JARVIK HEART REMAINS THE ONLY INSTITUTION IN THE PROGRAM, AND HAS RECEIVED IDE AND HDE WITH THE JARVIK 2015. (15MM)
- US TRIAL IS UNDERWAY
- EU TRIAL PROTOCOL IS UNDER REVIEW

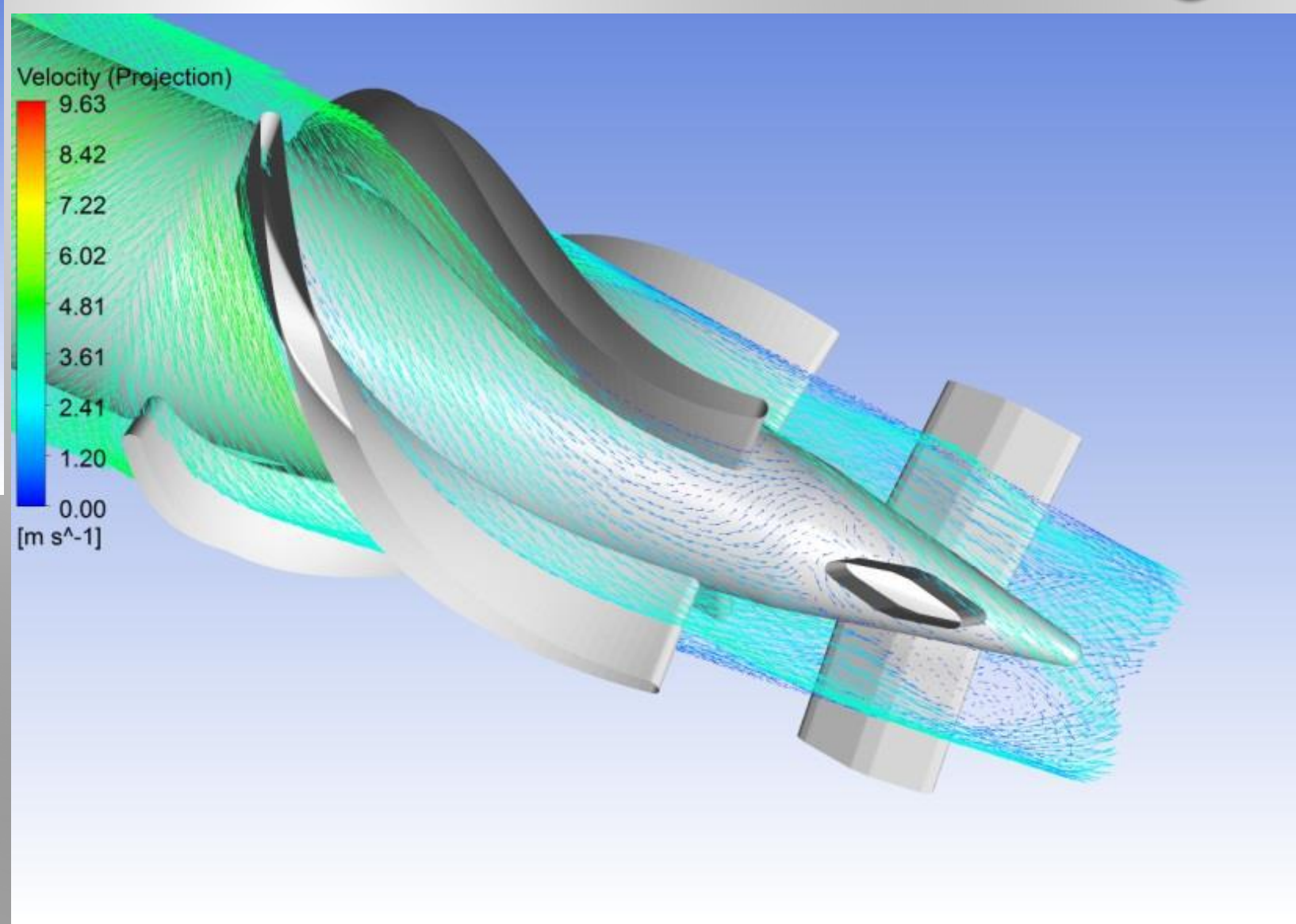
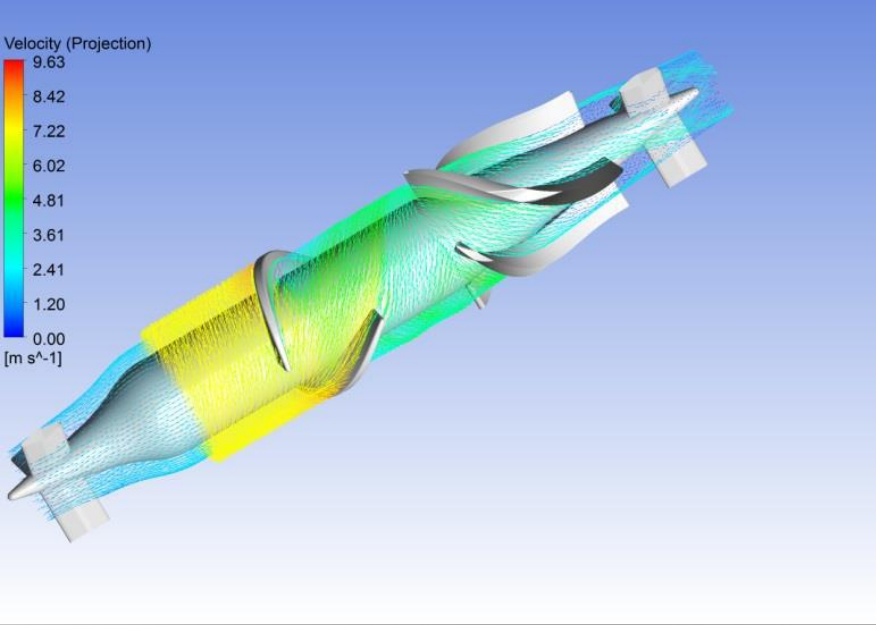




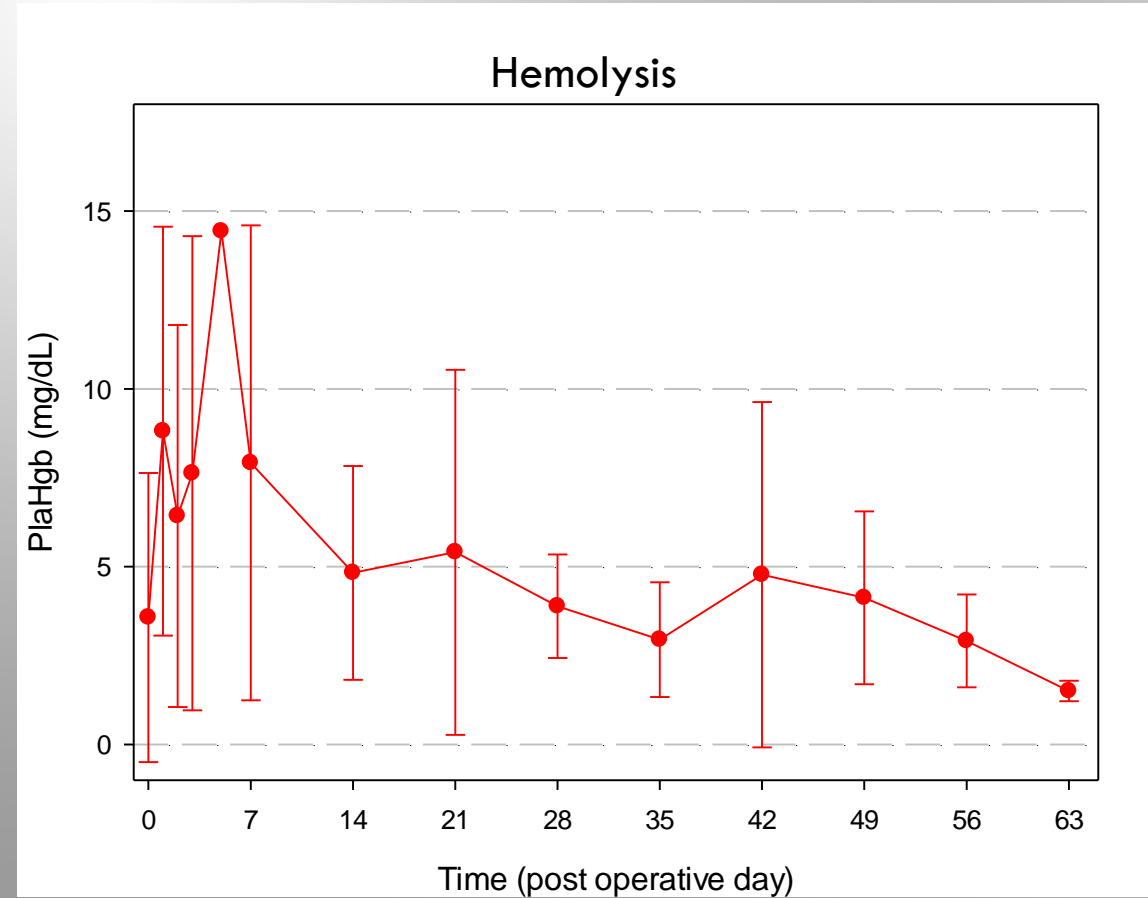
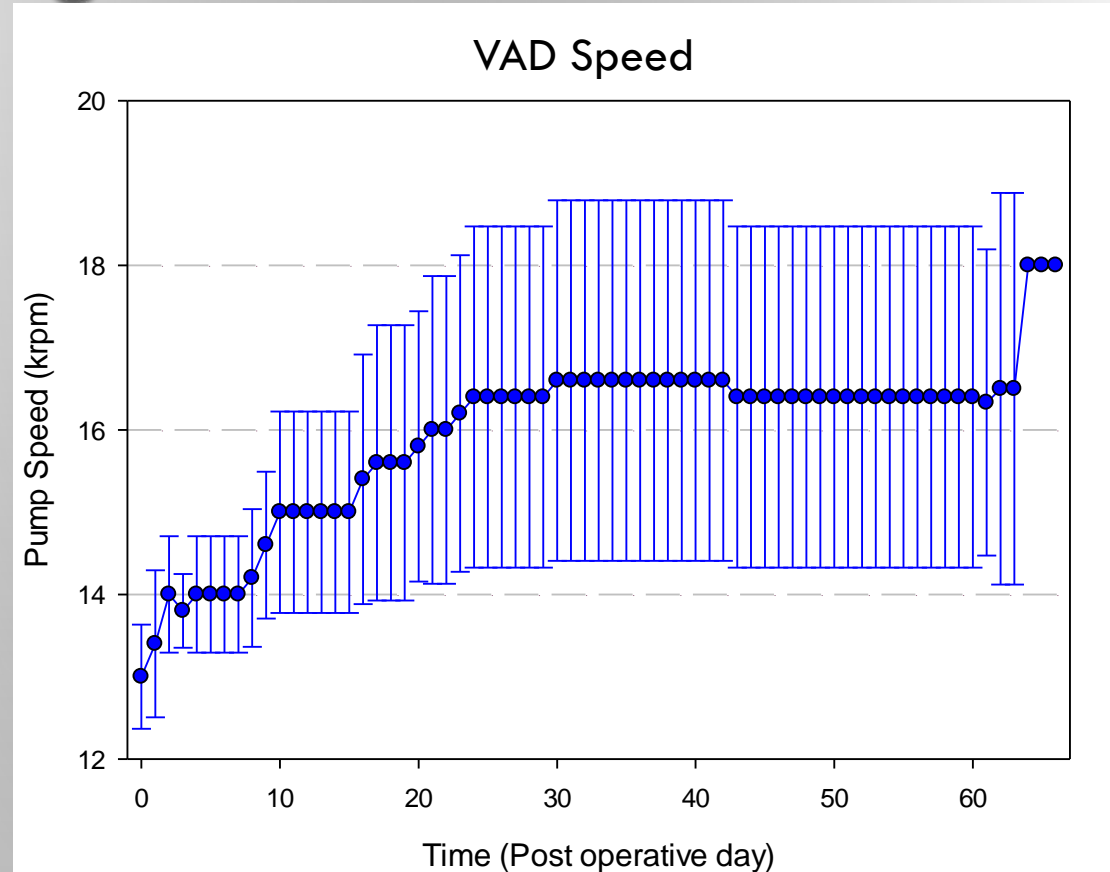
# CFD – WU (ADO) VELOCITY VECTORS @ 1.5LPM / 14,000RPM



# CFD – WU (ADO) VELOCITY VECTORS @ 3.5LPM / 18,000RPM



# IN-VIVO HEMOCOMPATIBILITY IN GLP ANIMAL STUDIES



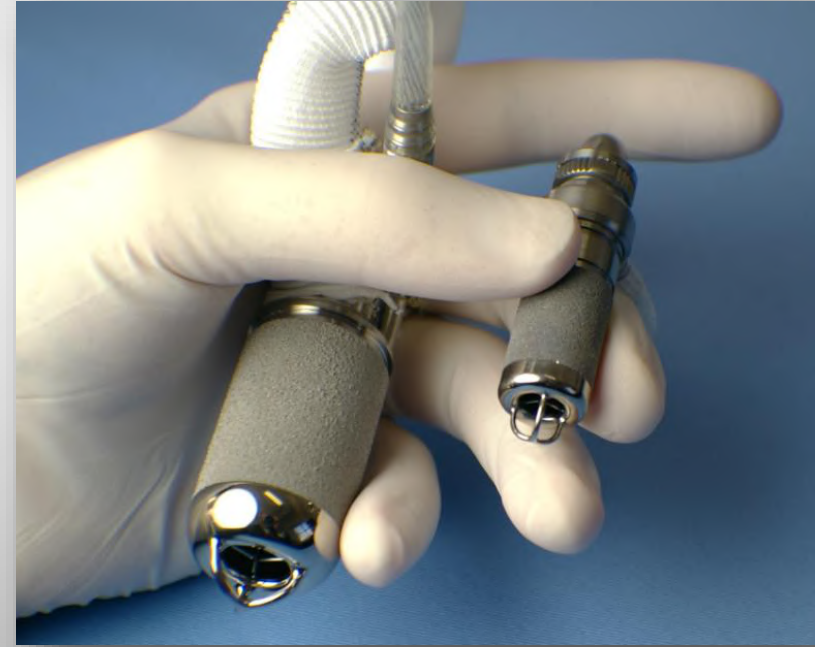
# Jarvik 15mm Overview

## Jarvik 15mm\*

- 15mm infant to adult LVAD or RVAD (1.0 to 4.0 Lpm)
- Jarvik 15mm unique technological features
  - Proven Jarvik Cone Bearings
  - Jarvik intraventricular placement
  - Proven Jarvik ILS controller and driveline options
  - Versatile ultra-small profile

### Multiple Clinical Approaches

- **Sternotomy**
  - LV to ascending aorta
  - RV to PA
- **Thoracotomy**
  - LV to descending aorta
  - LV to axillary artery
- **Mini thoracotomy and hemi sternotomy**
  - LV to ascending aorta
  - LV to axillary artery





Thank you