VAD MARKET WITHOUT HEARTWARE

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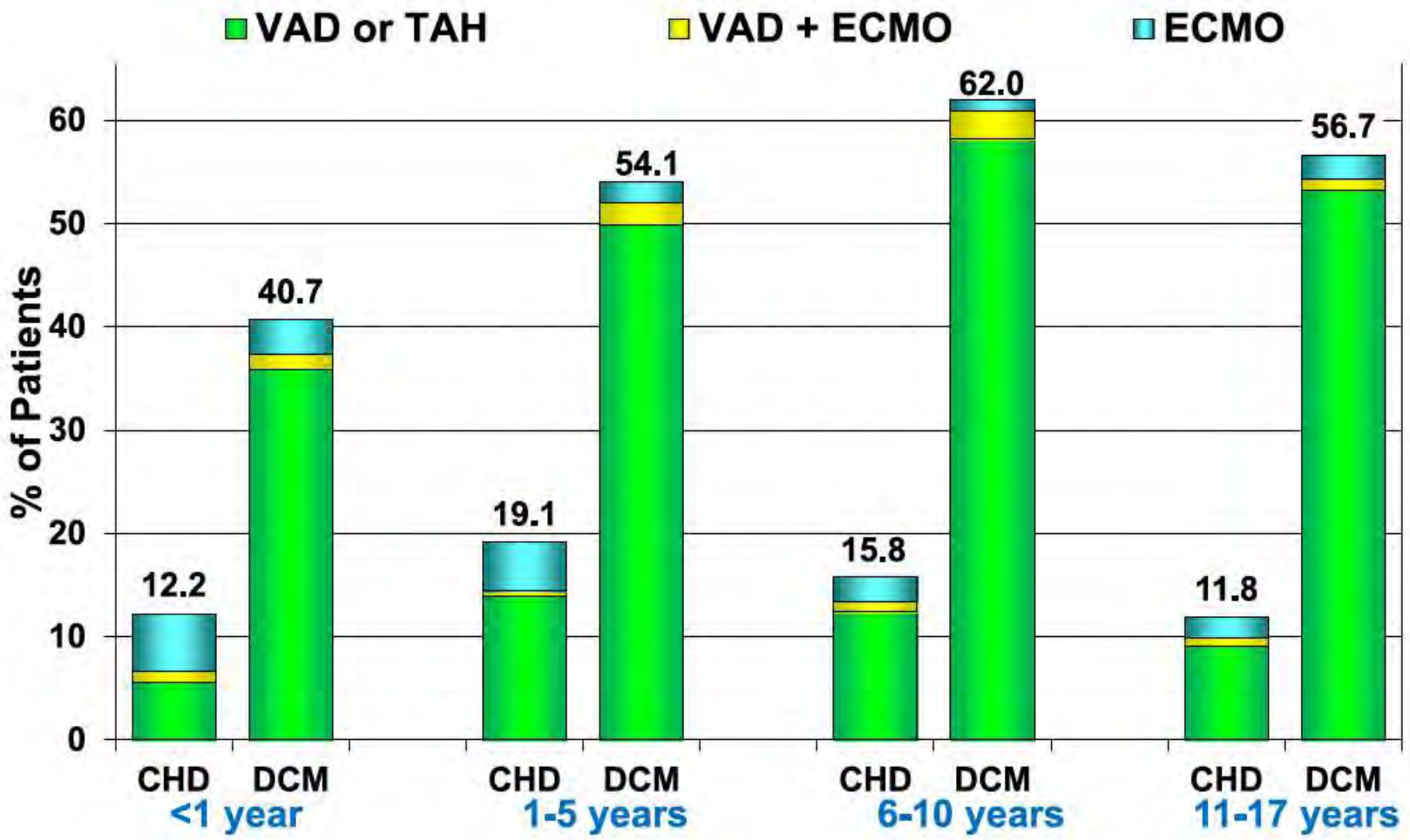
DISCLOSURES

- Consultant: Cytokinetics, Bayer, Merk, Myokardia
- Will discuss off-label use of ventricular assist devices (VADs)

TAKE HOME POINTS

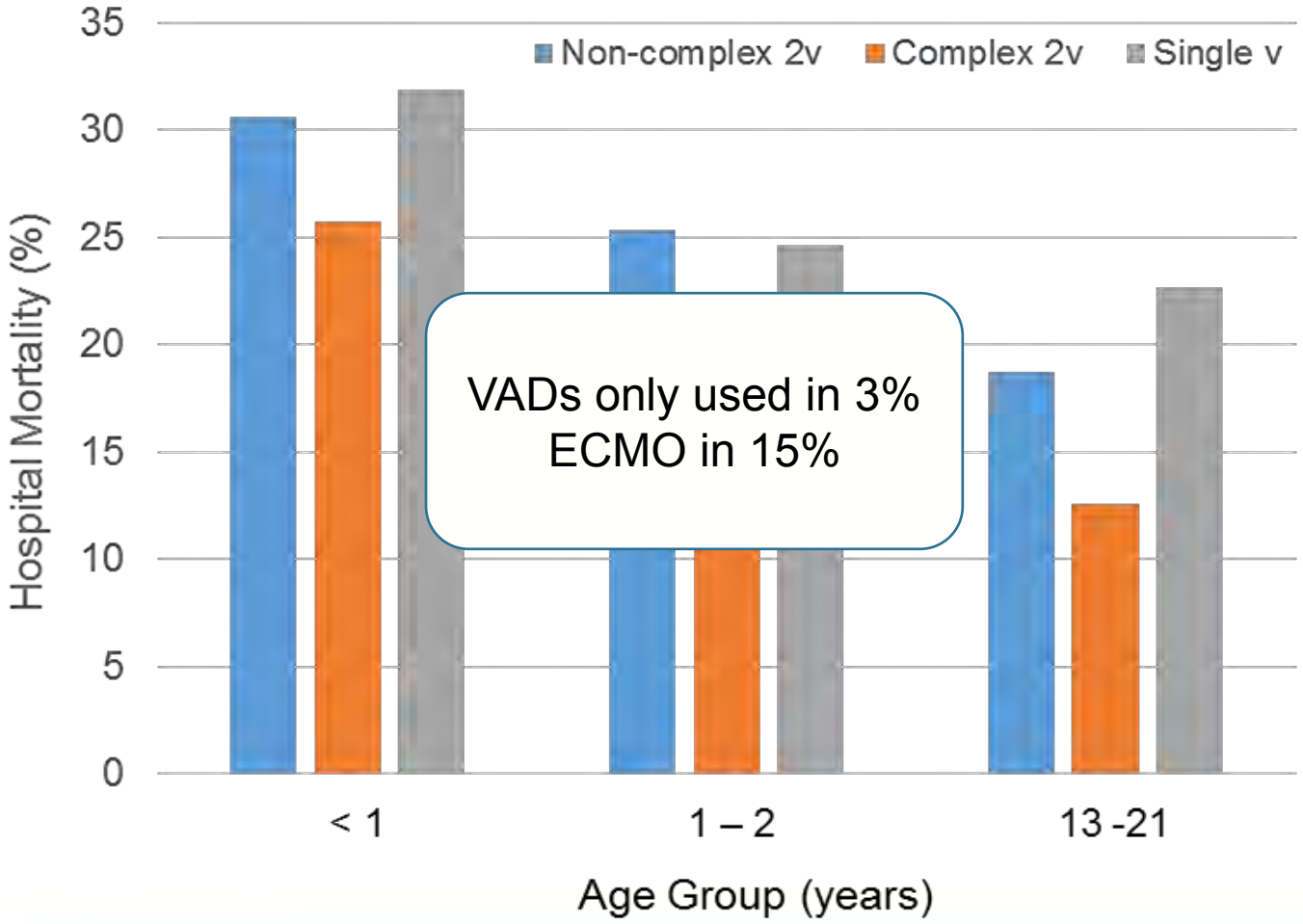
- HeartWare was an important device for children with heart failure
- HeartMate 3 is an excellent, approved device for children
- Still need better devices for small children and those with complex heart disease

VAD UTILIZATION IN CHILDREN



Rossano JW, et al. JHLT 2019

HOSPITAL MORTALITY IN HEART FAILURE WITH CONGENITAL HEART DISEASE



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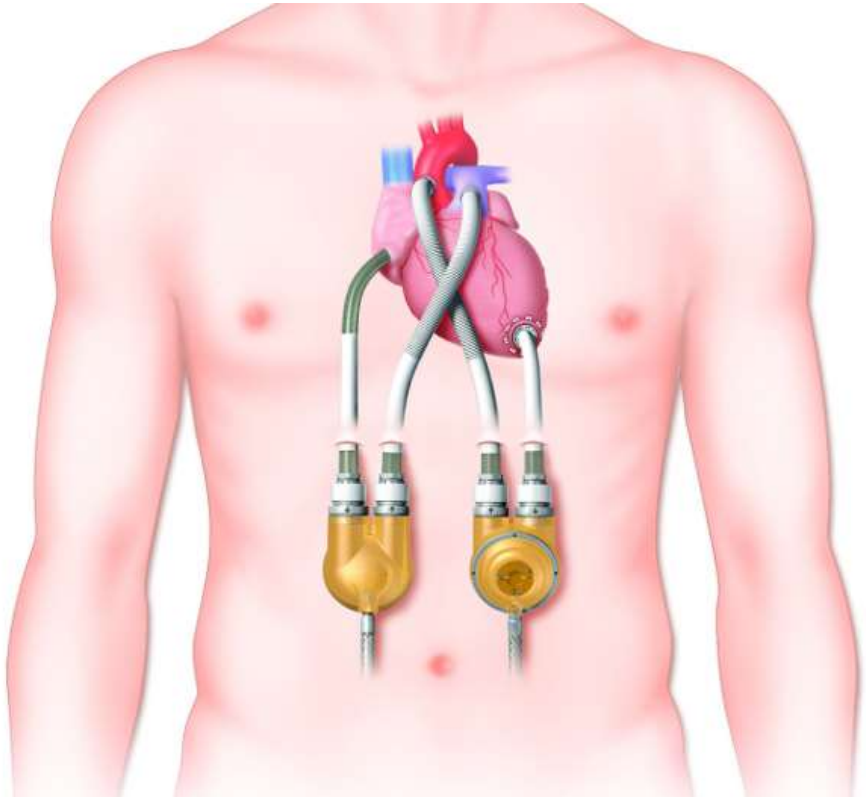
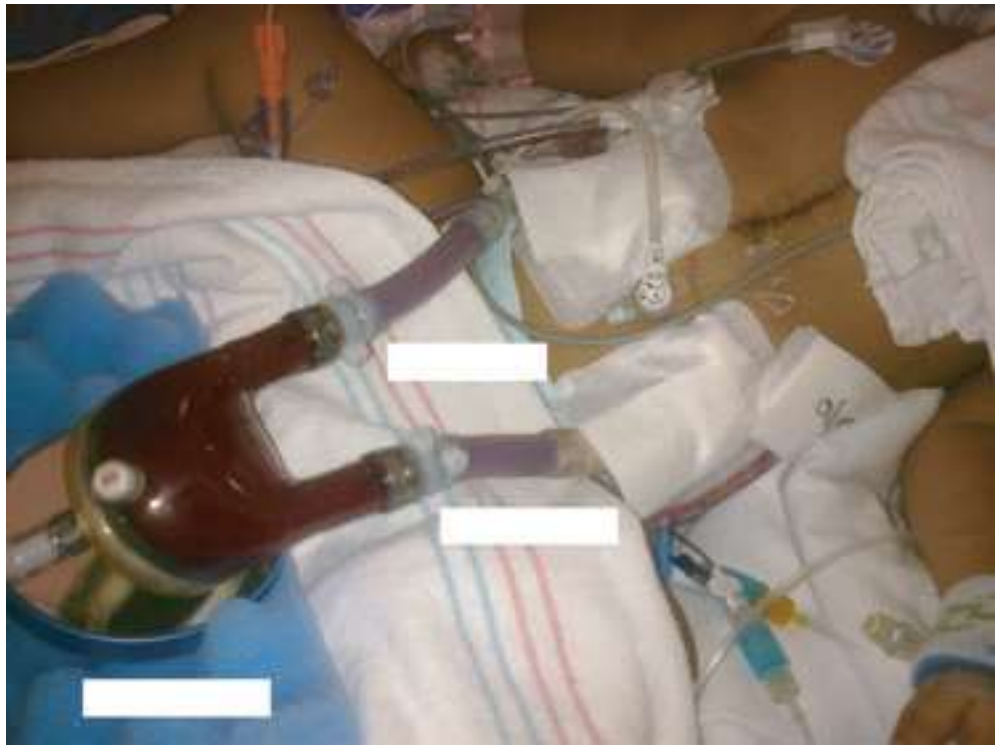
Burstein DS, et al. Am Heart J 2019

BERLIN HEART EXCOR VAD





BERLIN HEART

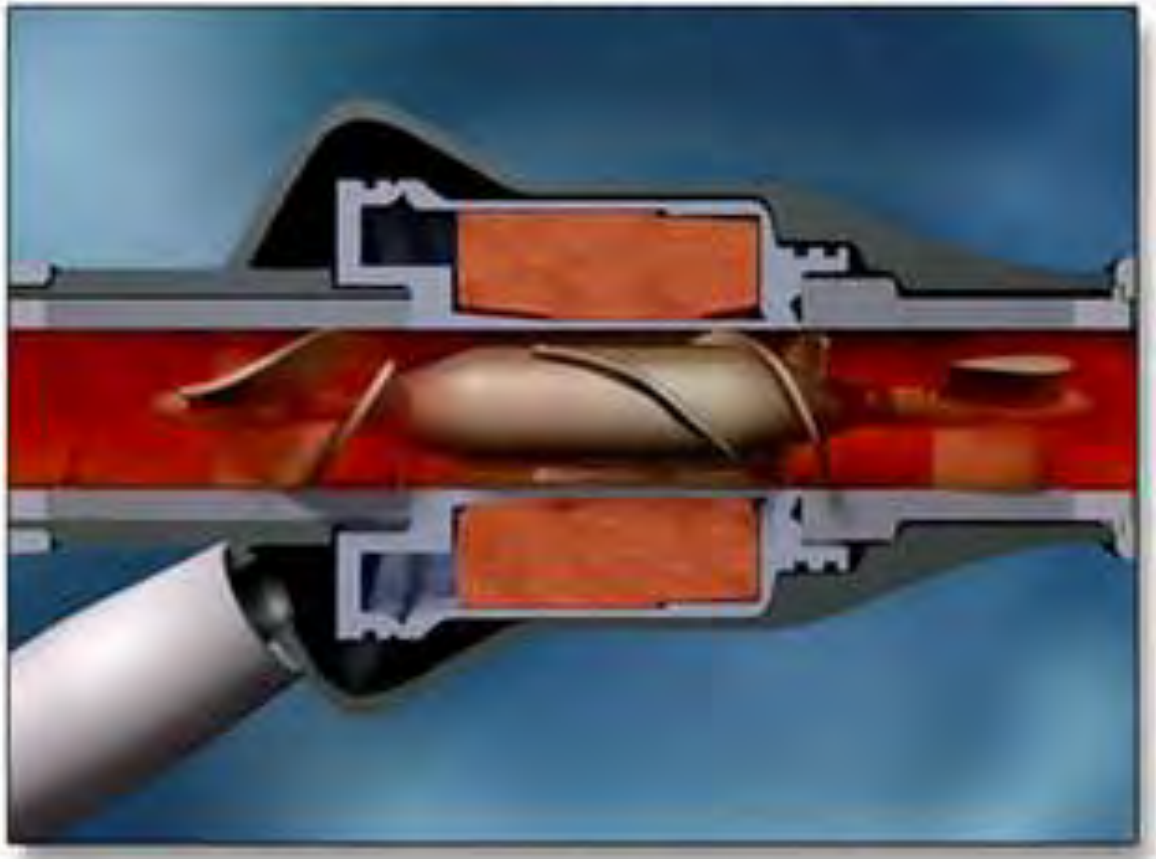
- In 2007 Investigational Device Exemption (IDE) granted
  - Device already widely utilized in Europe, Canada,
  - Many centers in United States also used regularly
- Humanitarian Device Exemption granted in 2012
- Post-approval study completed with 2020
- Estimated cost $15,000,000 - $17,000,000

Courtesy of Bob Kroslowitz

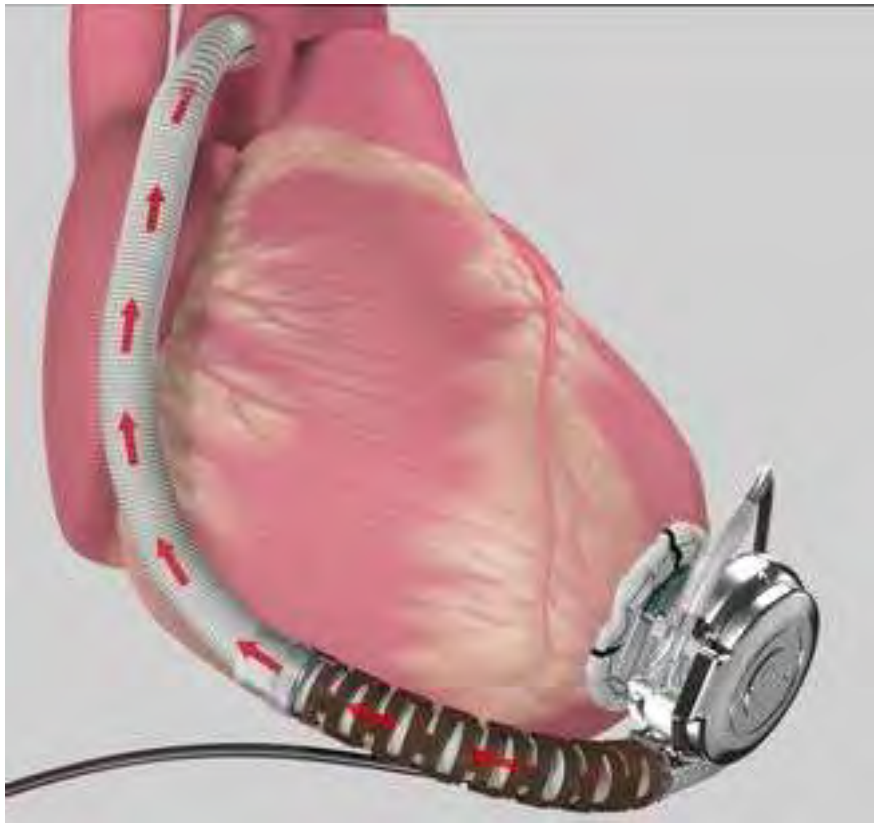
PULSATILE & CONTINUOUS FLOW VADS

Pulsatile / Volume Displacement

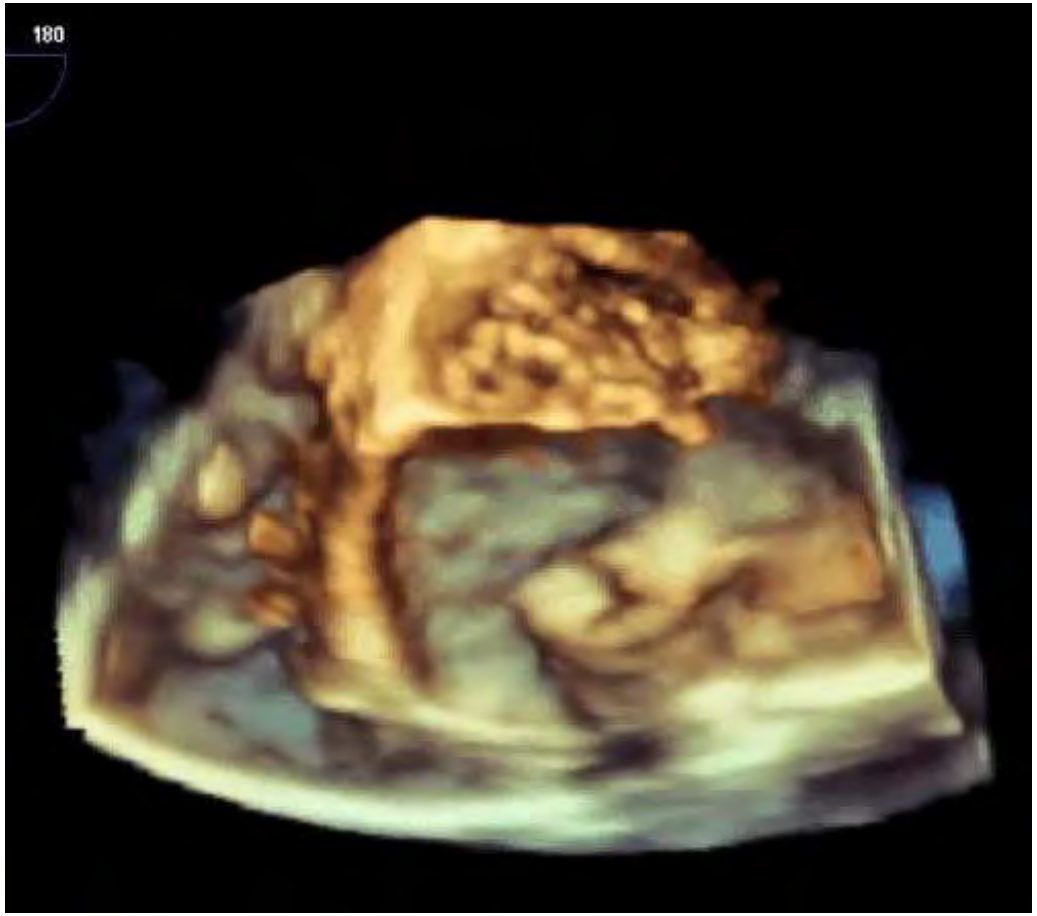
Continuous / Rotary

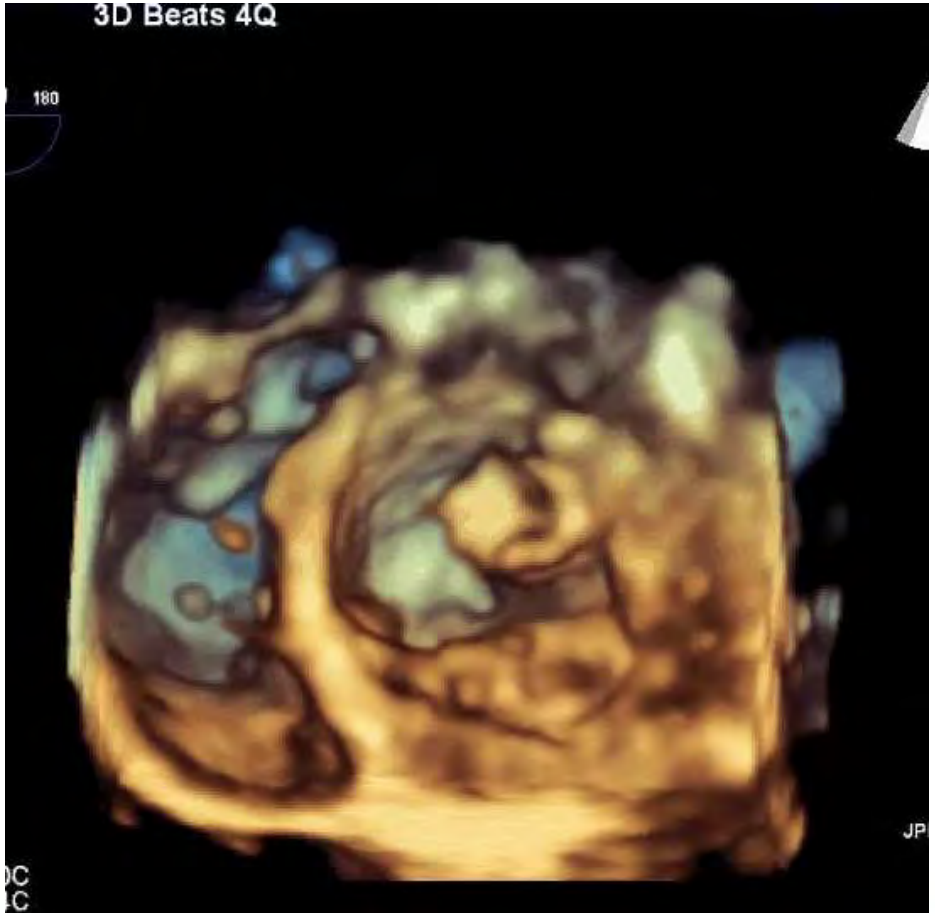


HEARTWARE



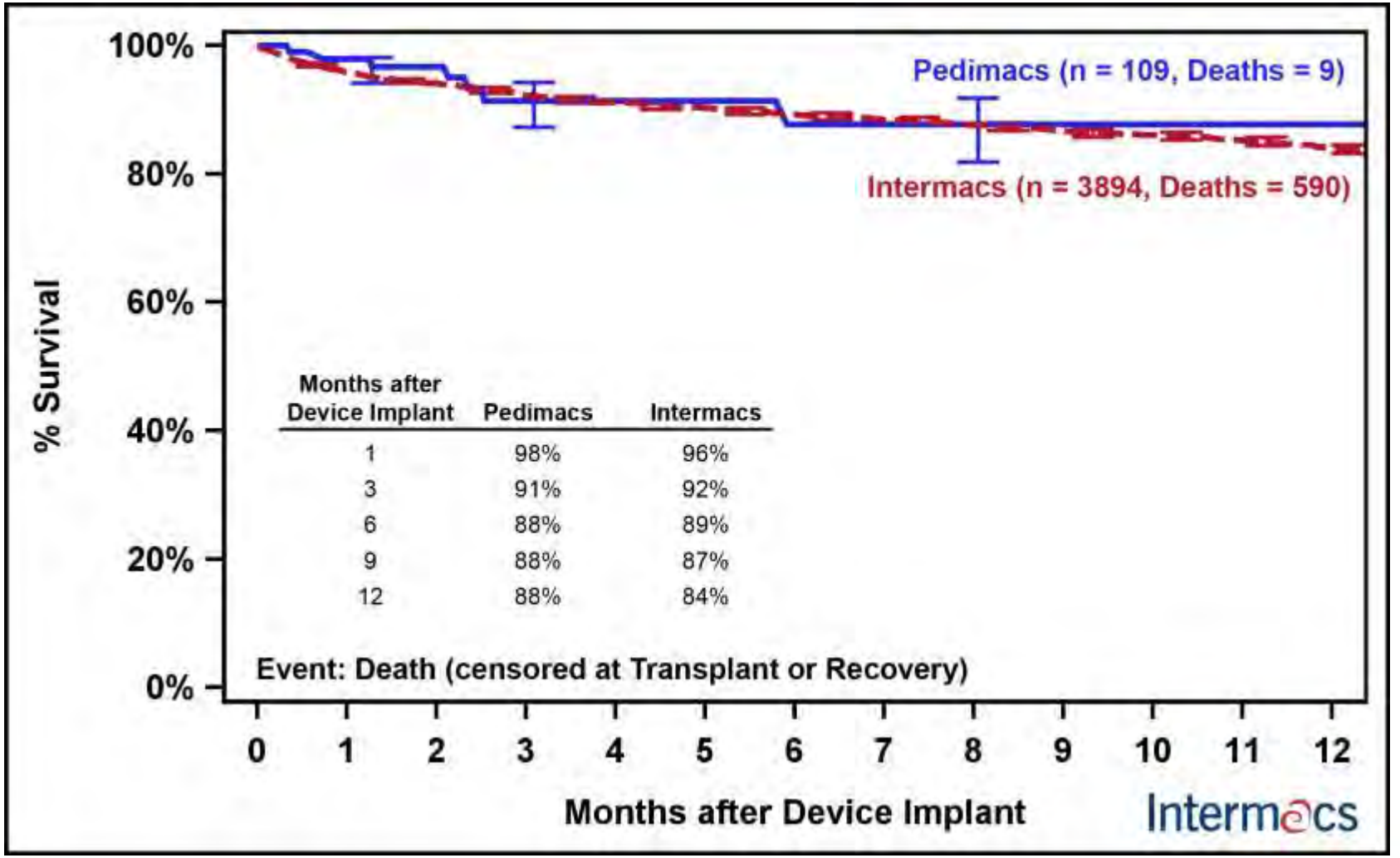
INTRAOPERATIVE ECHOCARDIOGRAM





LIFE OUT OF THE HOSPITAL

OVERALL SURVIVAL



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Rossano JW, et al. JHLT 2016

Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers

Letters to Health Care Providers

2022 Letters to Health Care Providers

2021 Letters to Health Care Providers

2020 Letters to Health

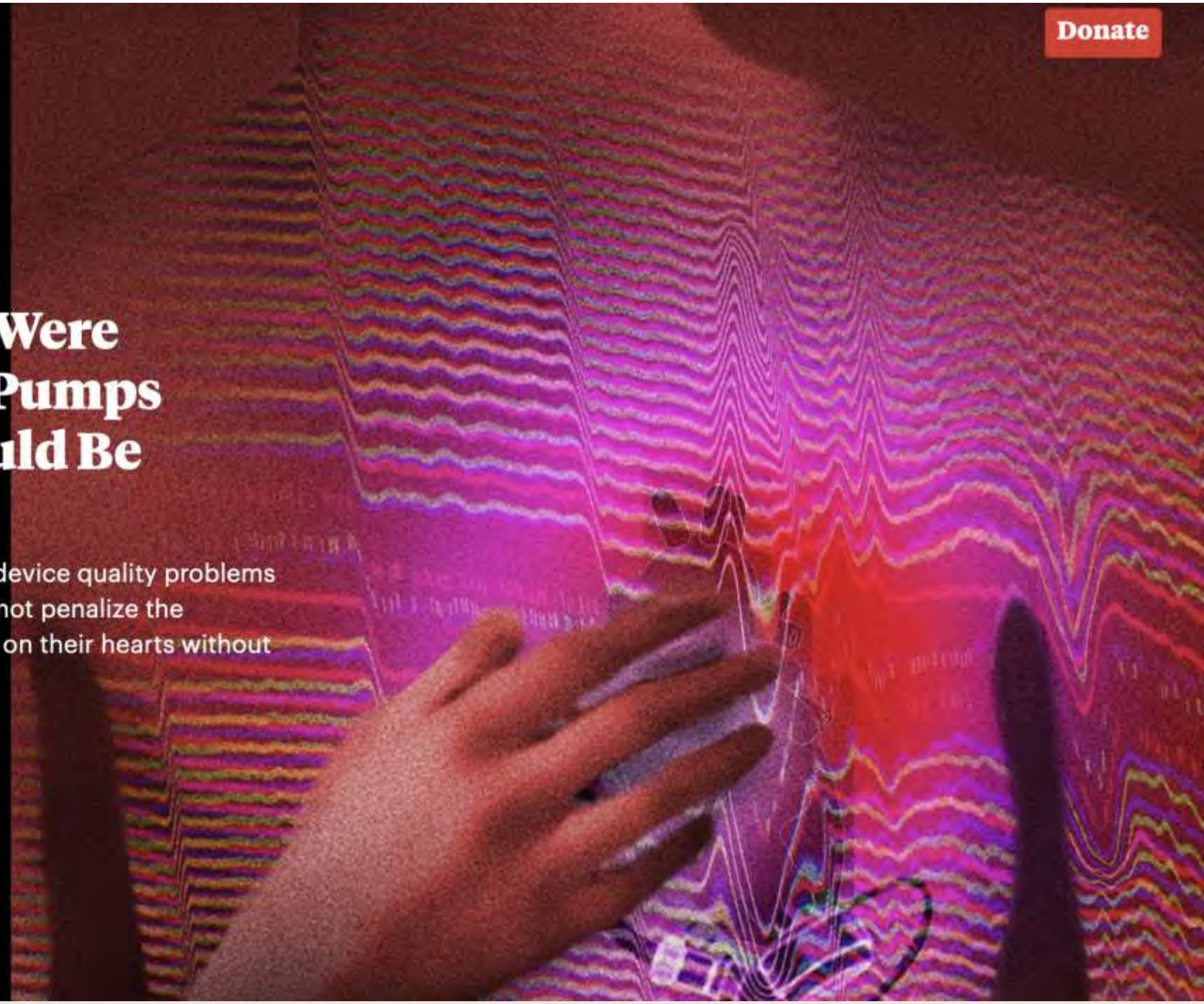
On April 28, 2022, the FDA issued a communication alerting health care providers to the possibility that patients who have the Medtronic HVAD System and appear to present with pump thrombosis may have a welding defect in the internal pump causing the pump to malfunction.

On August 6, 2021, the FDA identified the below Class I recall, the most serious type of medical device recall. Elective removal of properly functioning systems is not recommended at this time. Decisions about removing and/or exchanging the Medtronic HVAD System should be made by health care providers and patients on a case-by-case basis, considering the patient's clinical status and surgical risks.

Content current as of:
04/28/2022

Regulated Product(s)
Medical Devices

June 3, 2021



Health Care

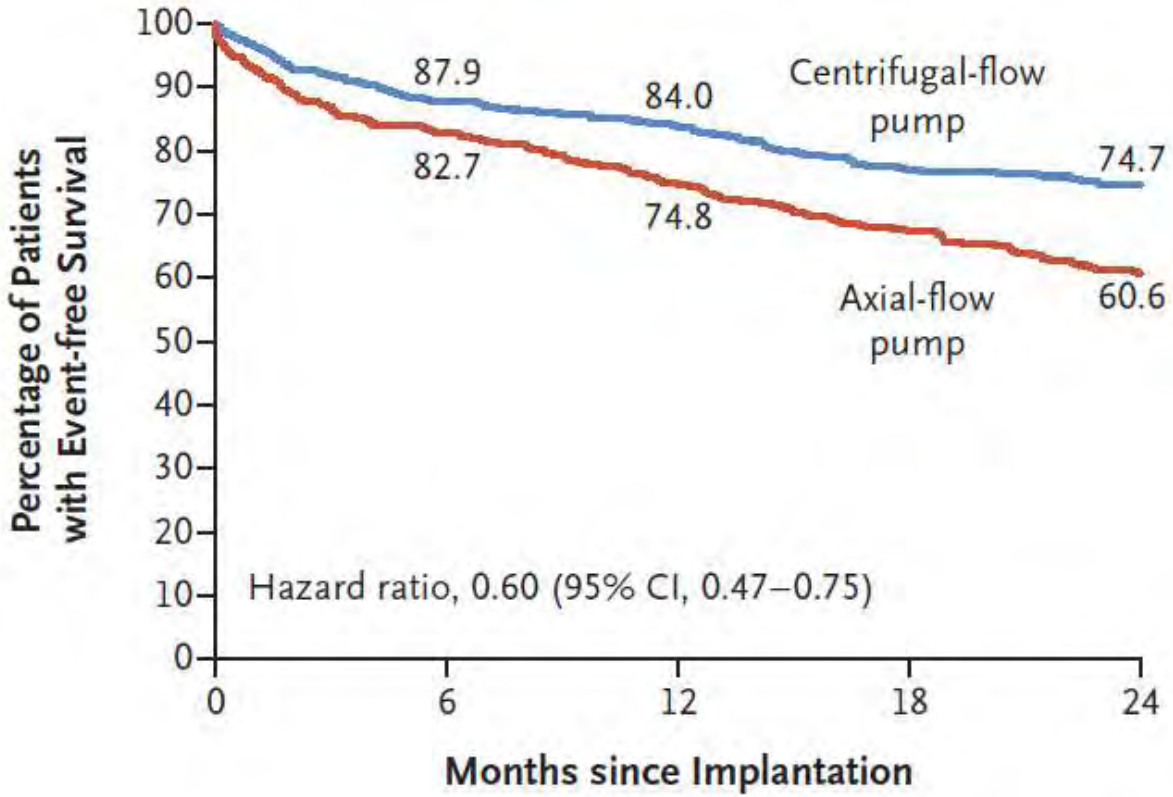
Thousands of Patients Were Implanted With Heart Pumps That the FDA Knew Could Be Dangerous

Inspectors repeatedly found manufacturing and device quality problems with the HeartWare heart pump. But the FDA did not penalize the company, and patients had the device implanted on their hearts without knowing the facts.

by Neil Bedi

Aug. 5, 2021, 5 a.m. EDT

HEARTMATE 3



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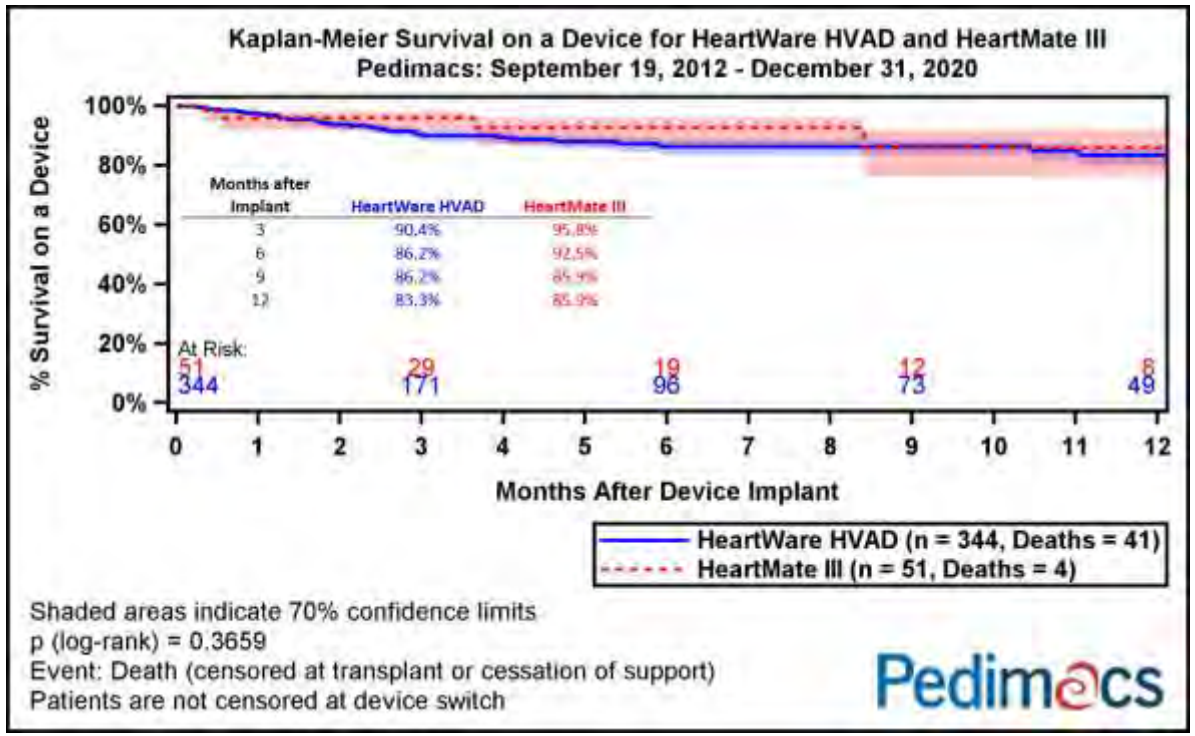
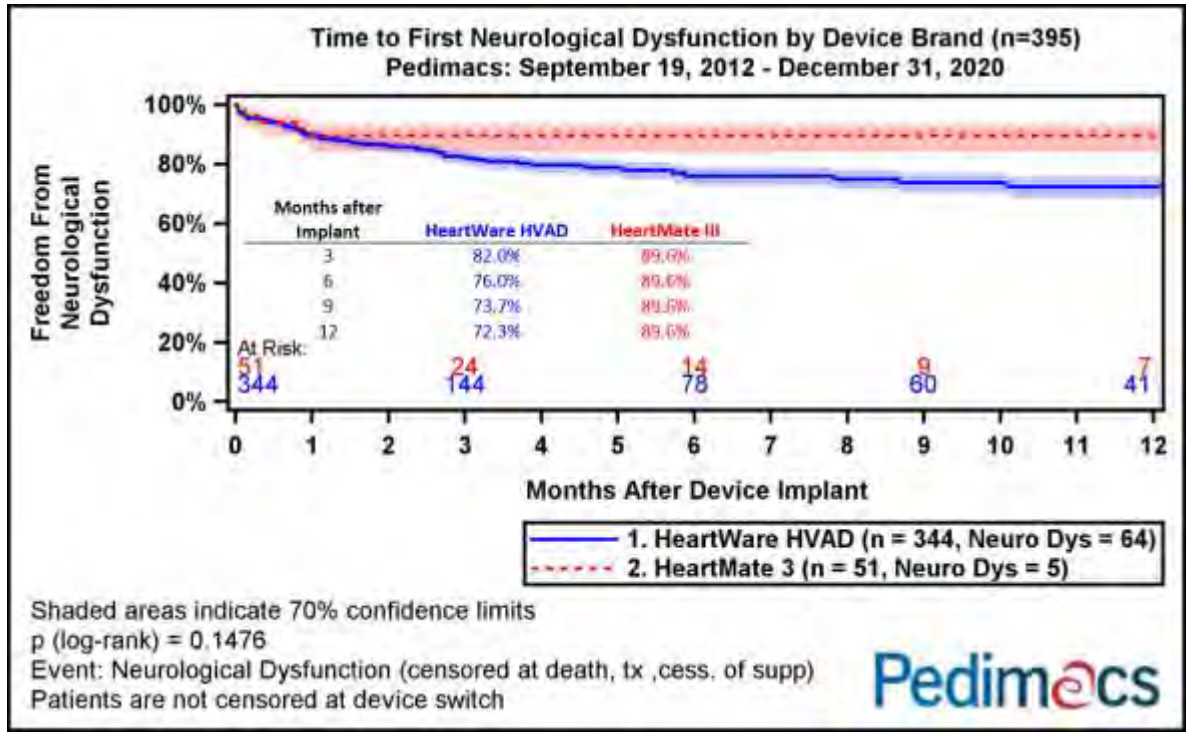
Mehra M, et al. NEJM 2019

Characteristics	HeartWare HVAD (n=344)	HeartMate 3 (n=51)	p-value
Age (y)	12.7 +/- 4.0	14.3 +/- 3.1	0.006
Age Group (y)			
< 1 year			
1-5 years	26 (7.6)		0.04
6-10 years	85 (24.7)	8 (15.7)	0.2
11-19 years	218 (63.4)	37 (72.5)	0.01
Weight (kg)			
<5 kg			
5-9 kg	1 (0.3)		0.70
10-20 kg	38 (11.0)	2 (3.9)	0.12
21-40 kg	98 (28.5)	12 (23.5)	0.46
41-70 kg	127 (36.9)	21 (41.2)	0.56
71-100 kg	61 (17.7)	8 (15.7)	0.72
>101 kg	19 (5.5)	8 (15.7)	0.01

Rossano JW, et al. Annals Thorac Surg. 2021

HEARTWARE VS HEARTMATE





HOME › NEWSROOM › PRESS RELEASES

PRESS RELEASES

BACK TO PRESS RELEASES

FDA APPROVES LABELING UPDATE FOR ABBOTT'S HEARTMATE 3 HEART PUMP FOR USE IN PEDIATRIC PATIENTS

- Abbott's HeartMate 3™ heart pump approved for use for pediatric patients battling advanced heart failure
- This life-saving technology provides new treatment option for underserved population

SUMMARY

- HeartWare was an important device for children with heart failure
  - Expanded continuous flow technology to smaller patients
  - Serious safety concerns raised
- HeartMate 3 is an excellent, approved device for children
  - Modest number of patients that would have been supported with HeartWare that are too small for HeartMate
- Still need better devices for small children and those with complex heart disease

THANK YOU

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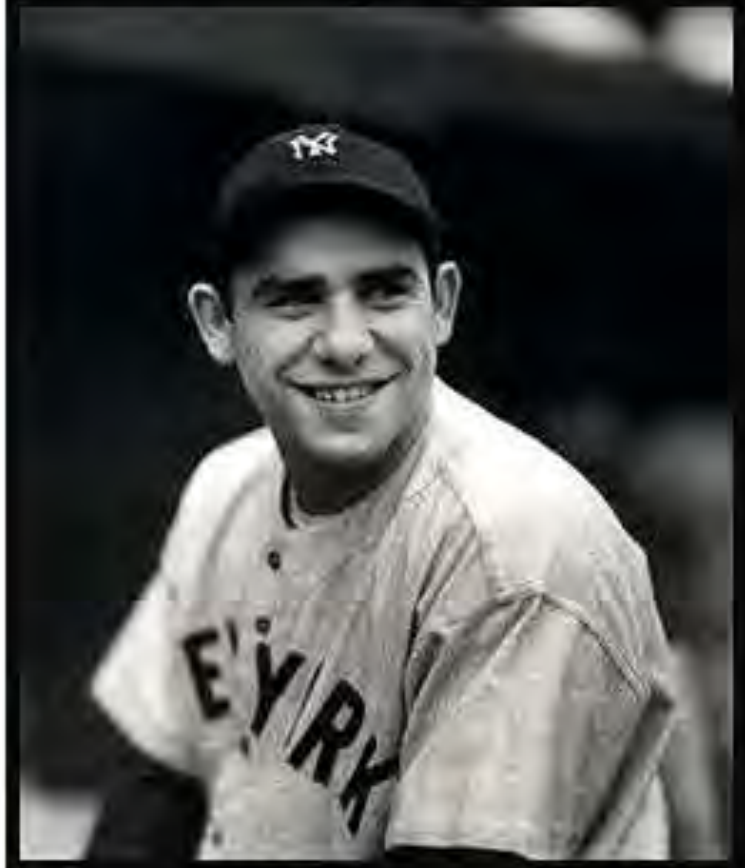


If you come to a fork in the road, take it.

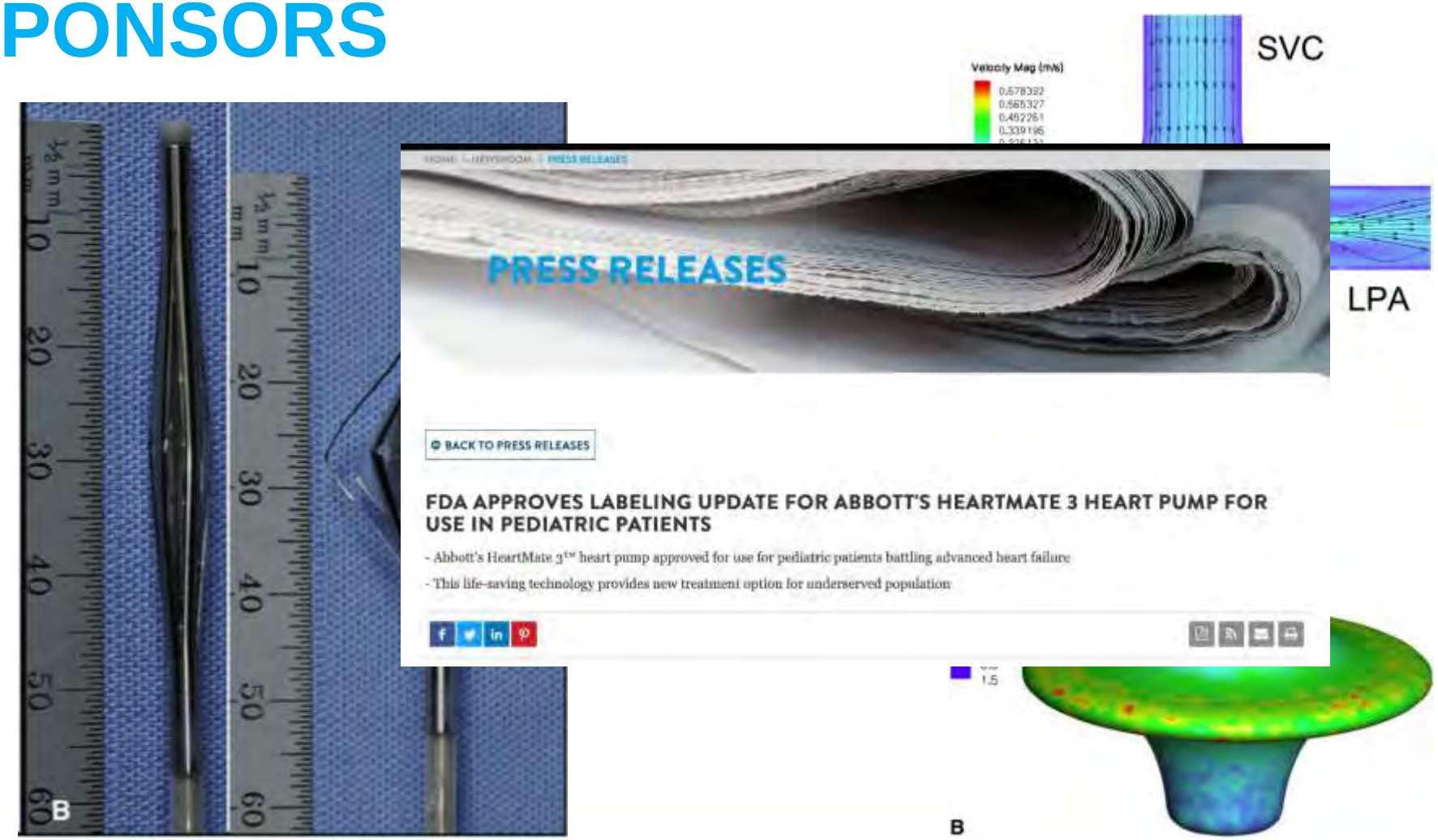
(Yogi Berra)

izquotes.com

TRANS-AORTIC VALVE REPLACEMENT (TAVR)

- Initial devices developed by start-up companies outside of US
- 9 years from first implant (France) to US approval
- 4 years from CE Mark to FDA approval
- US was 43rd country to receive approval
- 20,000-30,000 patients received TAVR worldwide before approval in US
- Medtronic and Edwards spent ~2 billion combined bringing the devices to market

VAD DEVELOPMENT & INDUSTRY SPONSORS



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Rodefeld MD, et al. JTCVS 2010