SUNSHINE HEART

Progress of the Fully Implantable System

TCT Conference, Oct 13, 2015 San Francisco

www.sunshineheart.com

Forward Looking Statement

- This presentation contains forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties. Various factors could cause actual results to differ materially from these statements including timing, clinical enrollment, clinical results, financing availability, product sales and marketing or efficacy of products, and the other risks set forth under the caption "Risk Factors" and elsewhere in our periodic and other reports filed with the U.S. Securities and Exchange Commission, including our Annual Report or Form 10-K for the fiscal year ended December 31, 2014.
- Although the Company believes that the forward-looking statements are reasonable and based on information currently available, it can give no assurances that the Company's expectations are correct. All forward looking statements are expressly qualified in their entirety by this cautionary statement.
- Caution: C-Pulse ® is an investigational device. The device is limited by federal (United States) law to investigational use only.
- C-Pulse is a registered trademark of Sunshine Heart Inc.

C-Pulse II Overview:

C-Pulse II - Fully Implantable System

Internal electro-hydraulic converter and TETS eliminate the percutaneous drive line and associated infection risks.

1. **Non-blood contacting**
2. **Non-obligatory**

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1. **Non-blood contacting**
2. **Non-obligatory**
3. ***No percutaneous drive line***
4. ***No implanted battery***

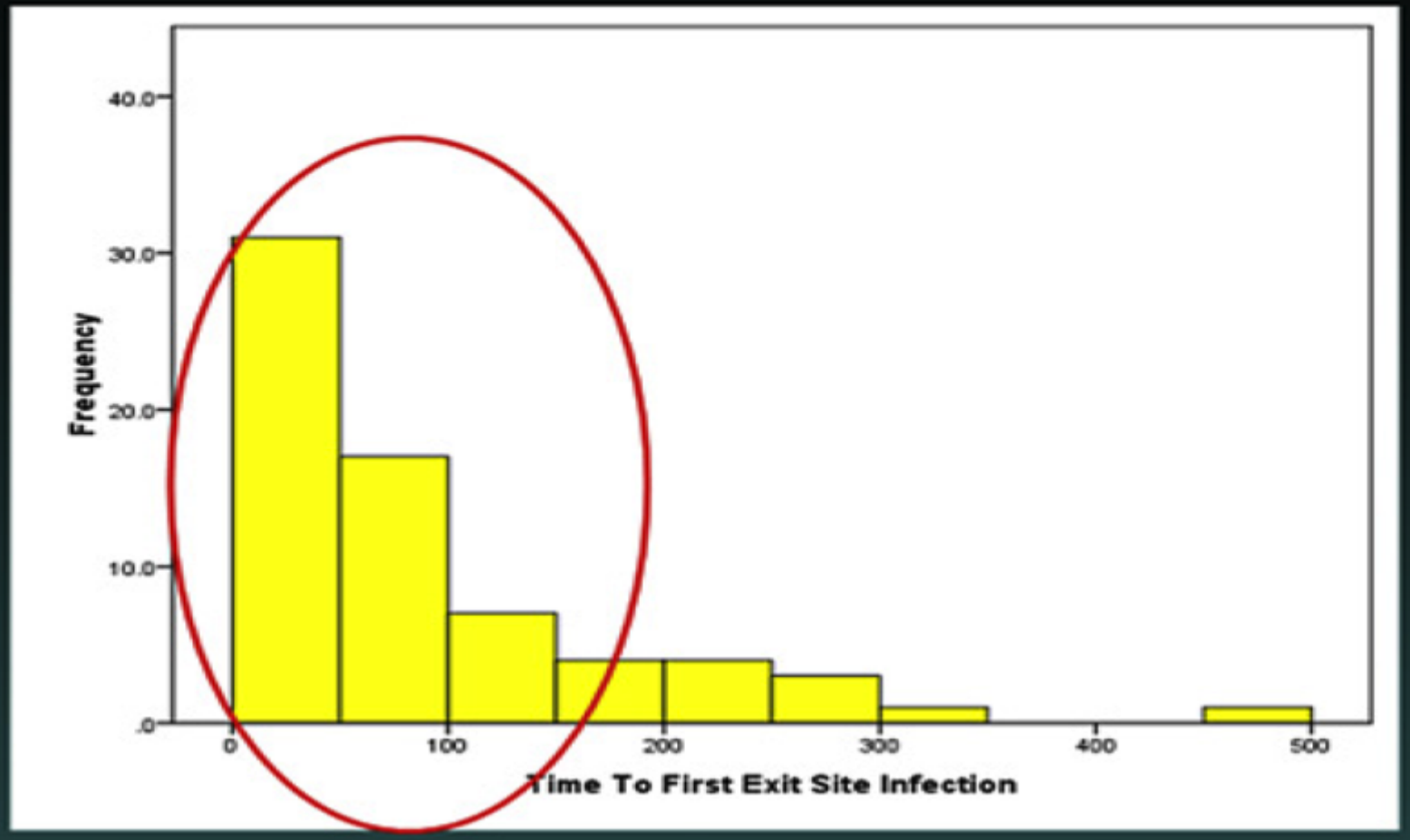
Freedom From VAD Exit Site Infection
01/01/1996 to 12/31/2008

ESI/ 100 pt-Months

	Entire Cohort
0-3 mo	9.22
3-6 mo	8.18
6-12 mo	5.38

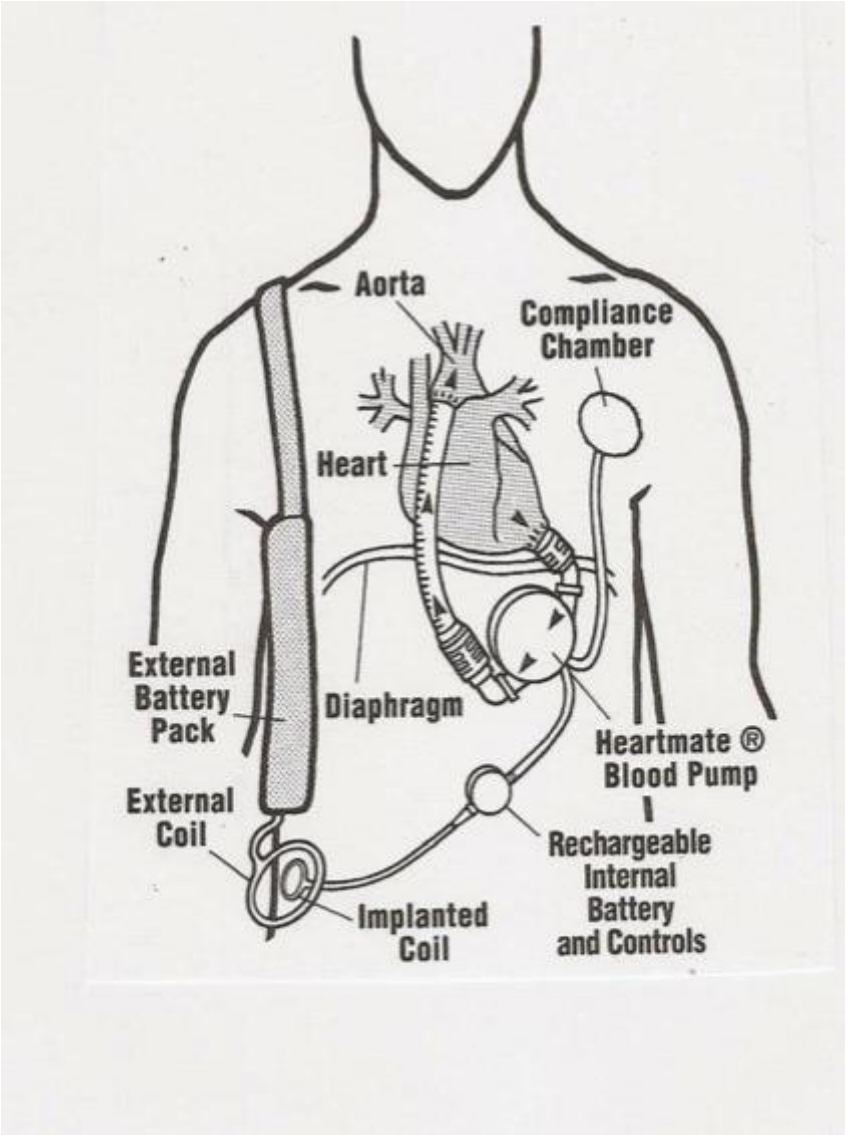
Pramod Bonde *et al.* Yale University

Distribution of Initial VAD Exit Site Infections 01/01/1996 to 12/31/2008



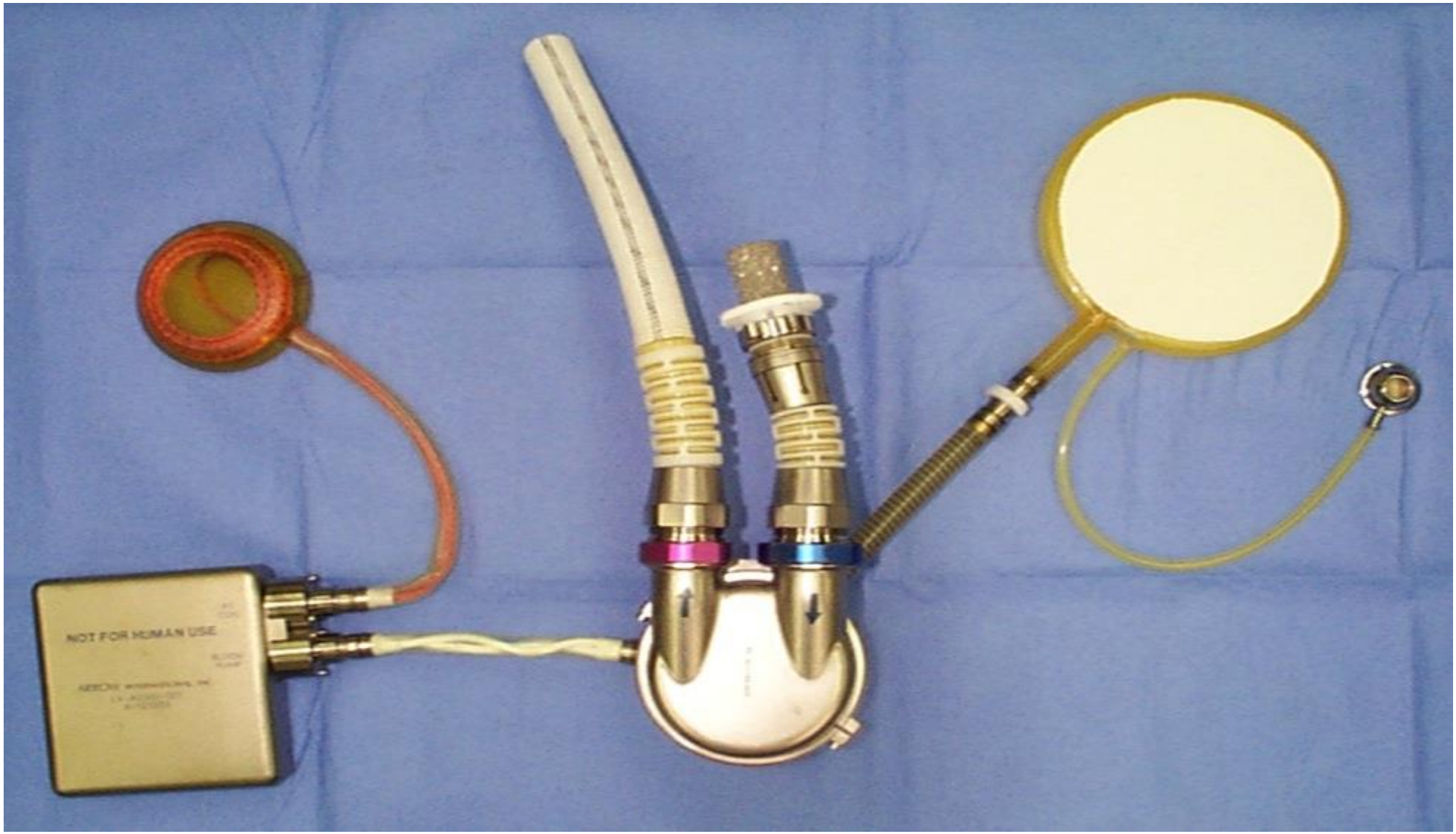
Pramod Bonde *et al.* Yale University

Eliminating the driveline is *not* a new idea…

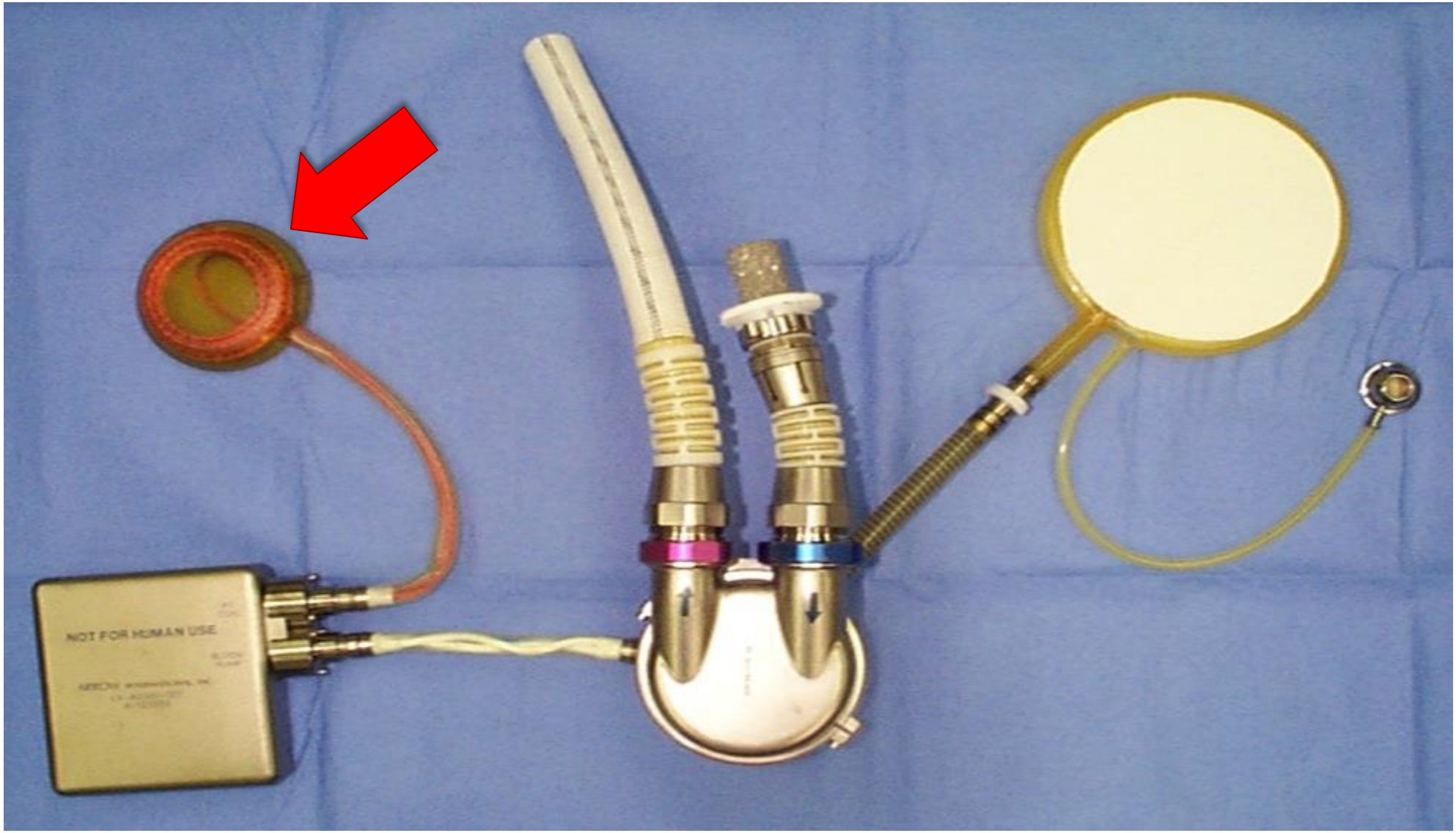


Circa 1985

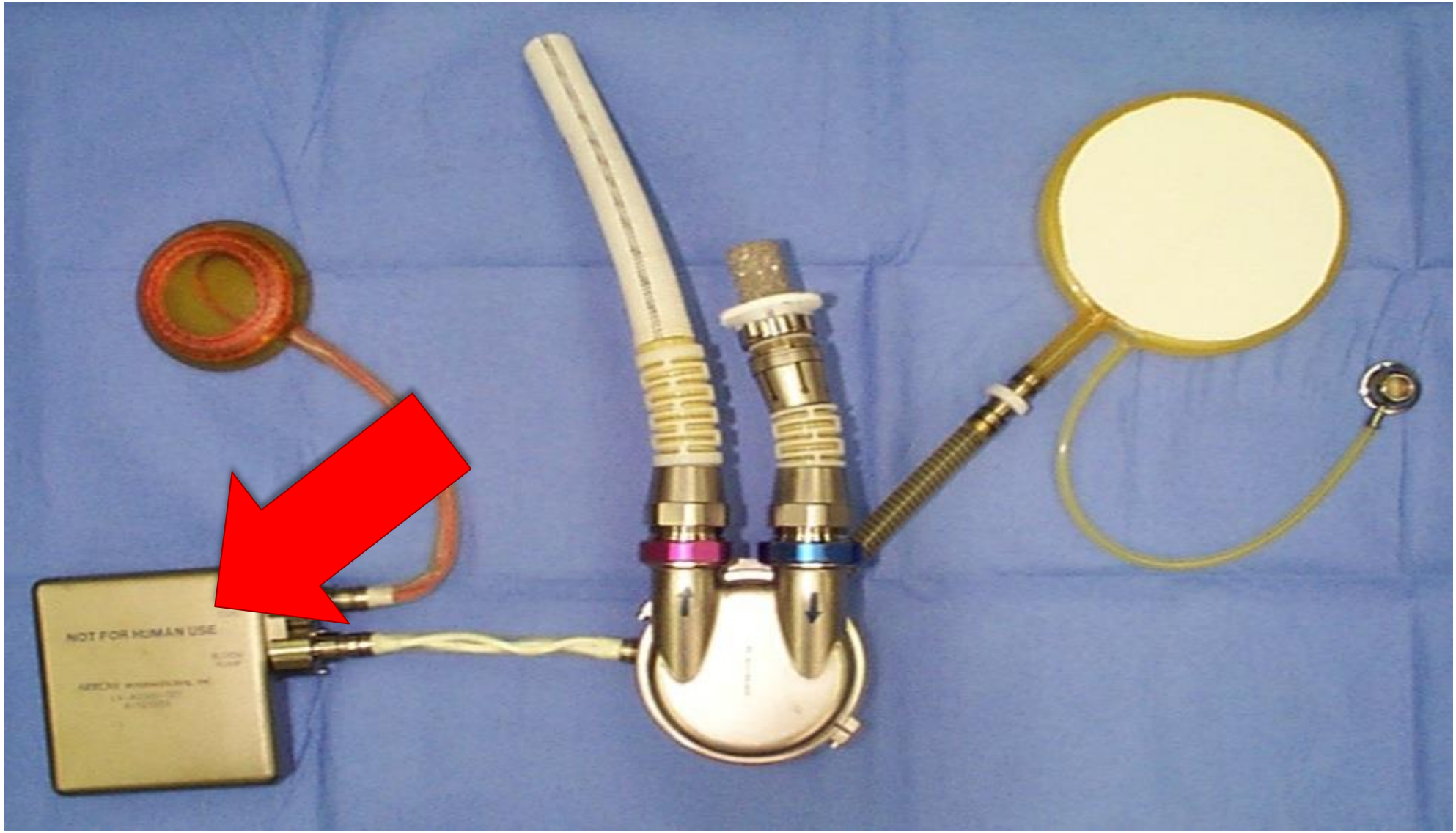
Arrow LionHeart LVAD



Arrow LionHeart LVAD



Arrow LionHeart LVAD



Penn State Arrow Lionheart

summary Nov 9, 2003

- 23 male patients enrolled between Oct 1999 and Dec 2002
- 10/23 discharged home with device
- 8/23 alive at 2 years
- 1/23 alive at 3 years
- Mean duration 347 days (17-1259)
- 5/23 serious infections (.17/patient year vs. .60/patient year REMATCH… no deaths due to infections)
- No serious TETs complications

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Where will clinical implementation of TETS technology first find traction?

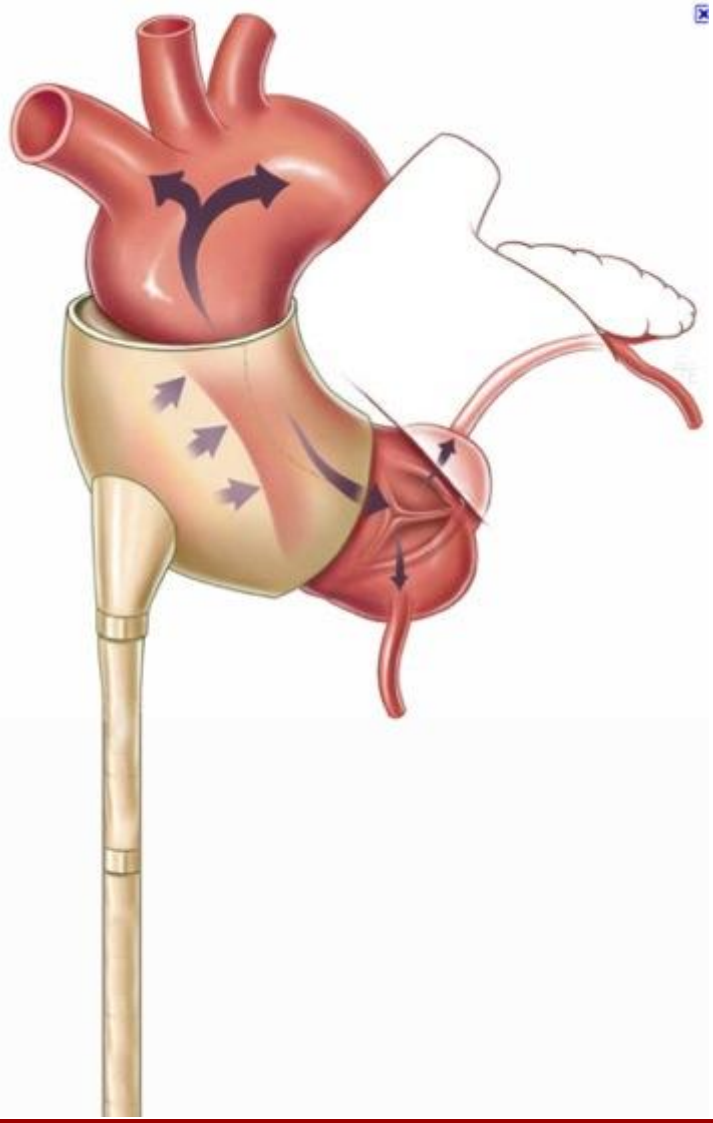

HEART
Assist 5


Berlin Heart

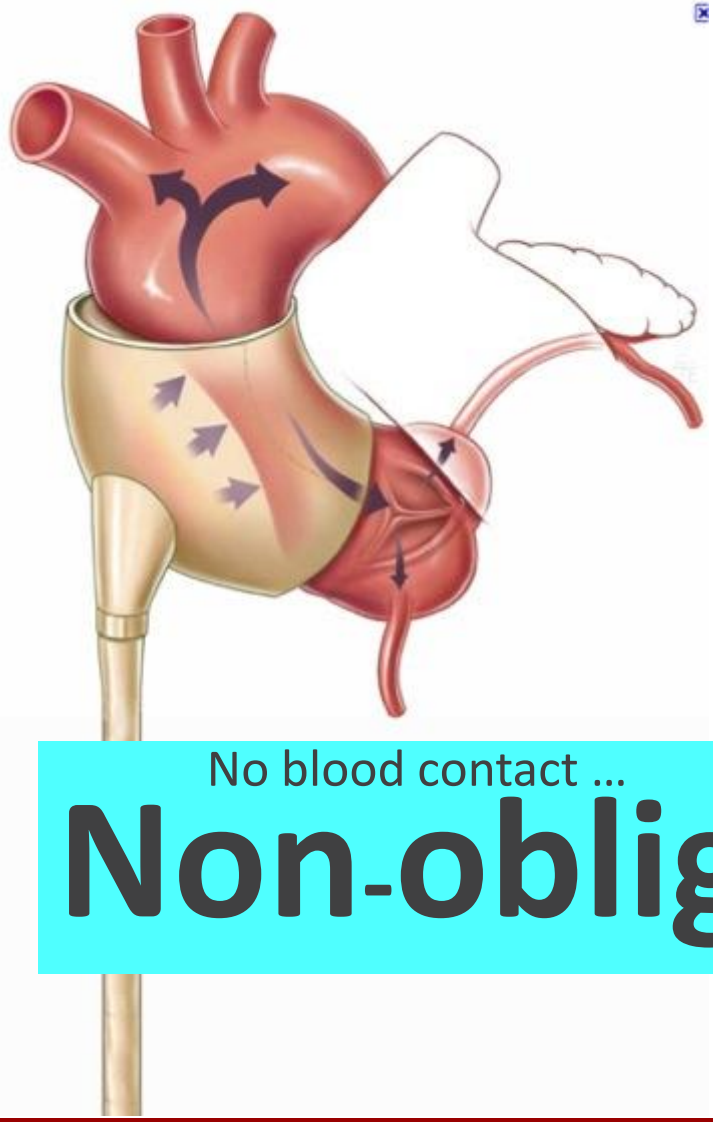

HEART
Assist 5


Berlin Heart

SUNSHINE HEART C-pulse extra-aortic balloon cuff



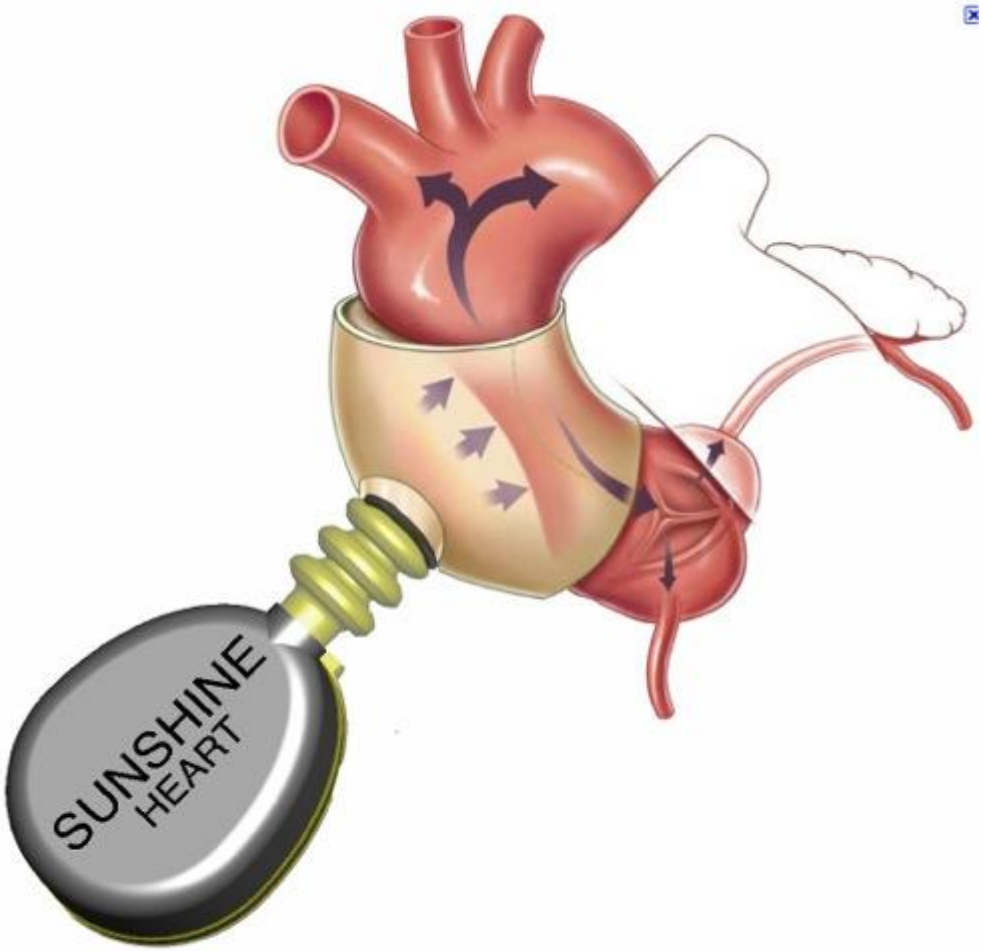
SUNSHINE HEART C-pulse extra-aortic balloon cuff

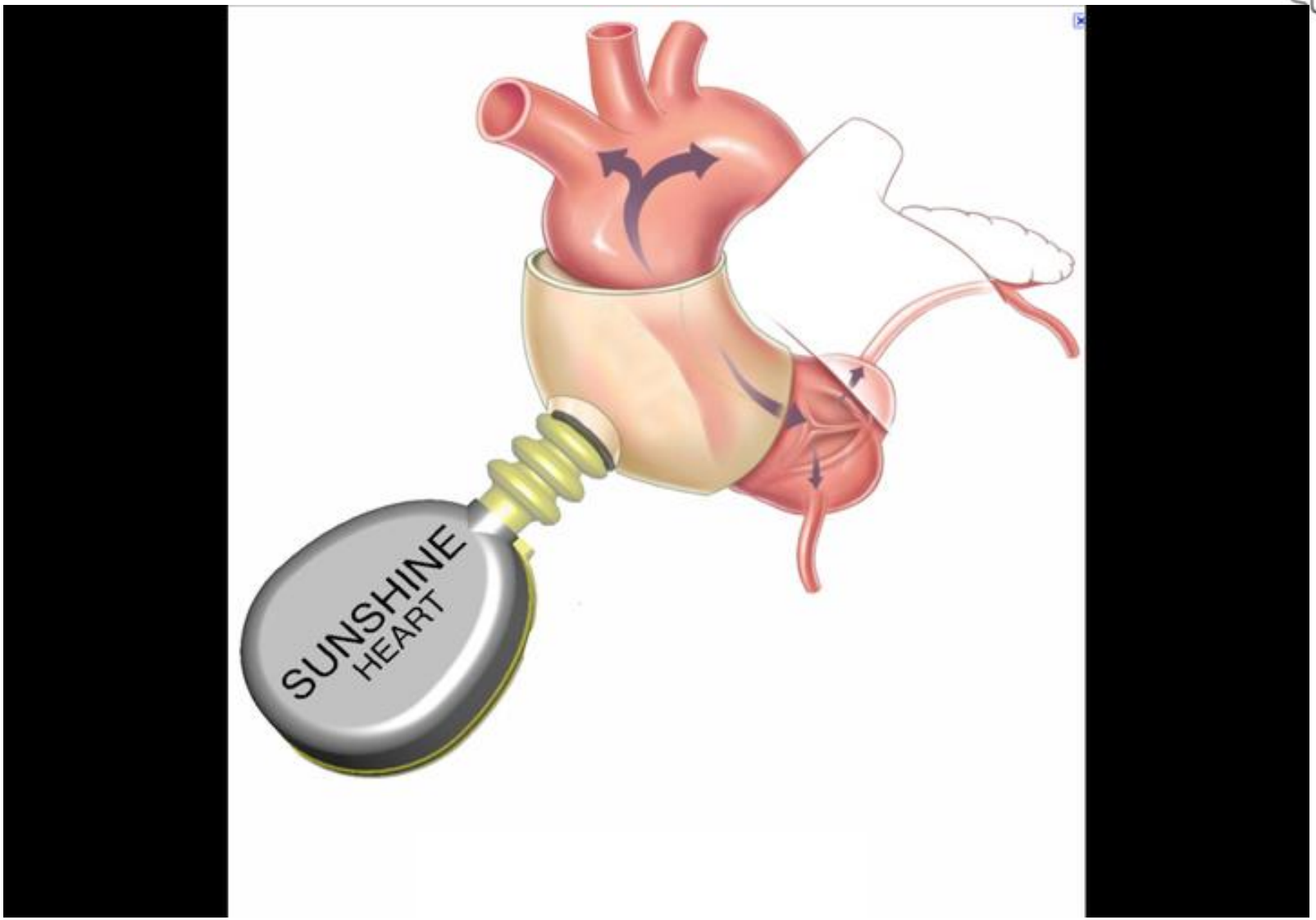


No blood contact …

Non-obligatory

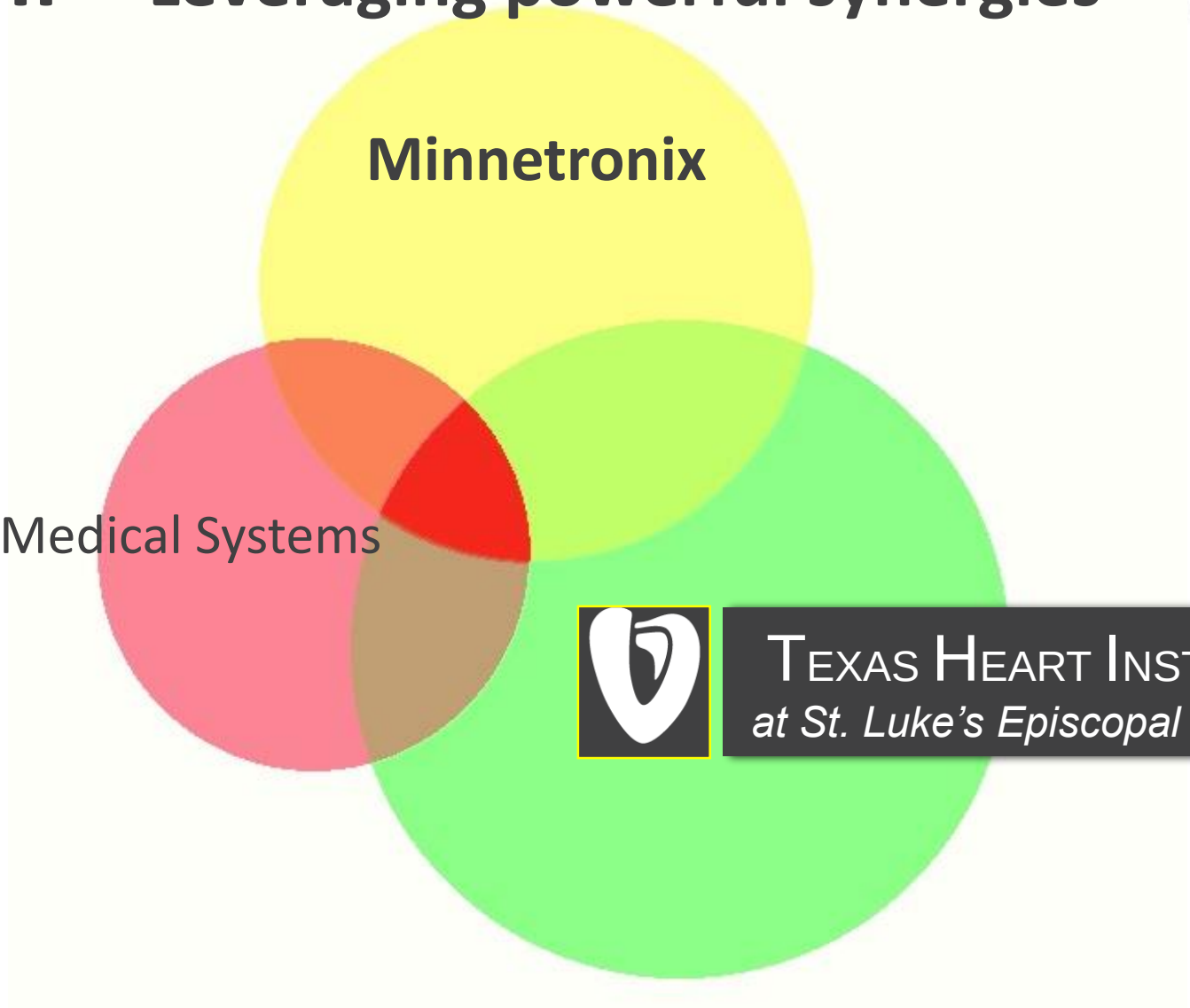
SUNSHINE HEART C-pulse II




SUNSHINE
HEART

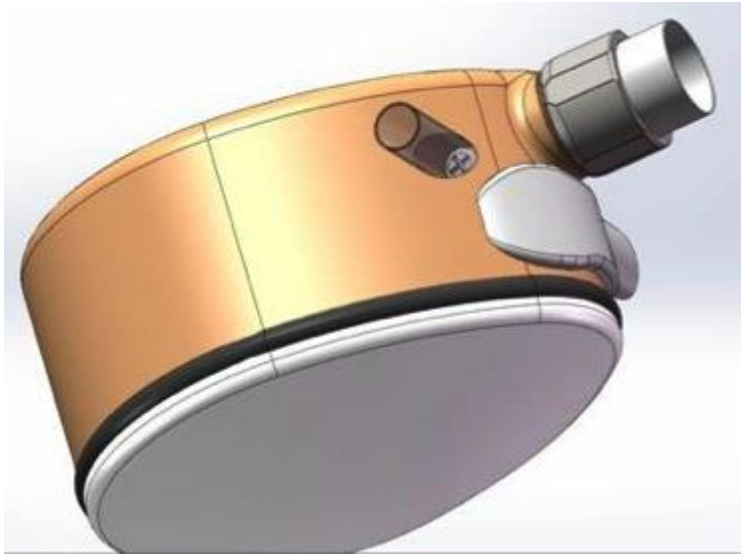
Electrohydraulic pump…

C-Pulse II – Leveraging powerful synergies



Electrohydraulic pump- *Cirtec* Medical Systems

- Rapidly inflates and deflates extra-aortic balloon cuff (reproduces C-I physiology)
- EKG synchronized to provide counter-pulsation
- Balloon passively empties in the event of pump or power failure (essential)
- Leverages the incompressibility of silicone oil
- Compliance reservoir incorporated into the base of the pump



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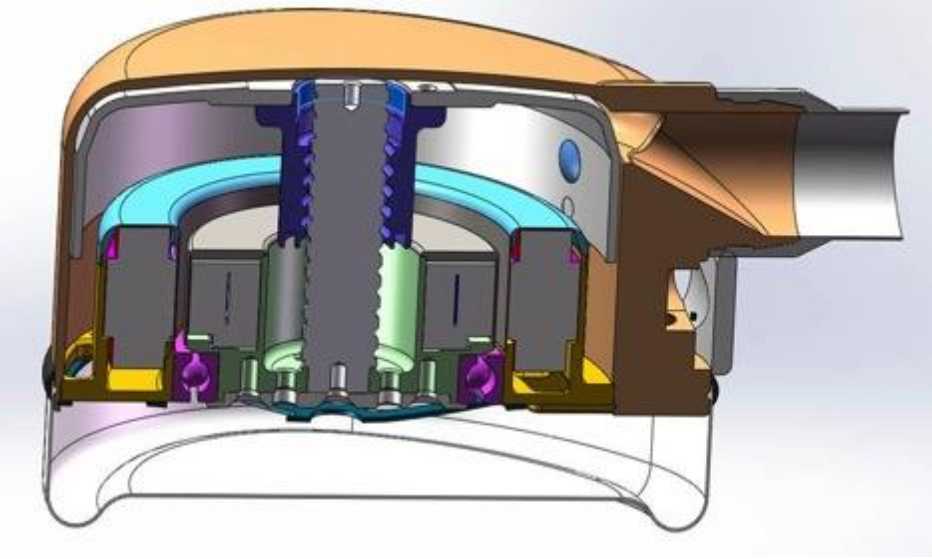
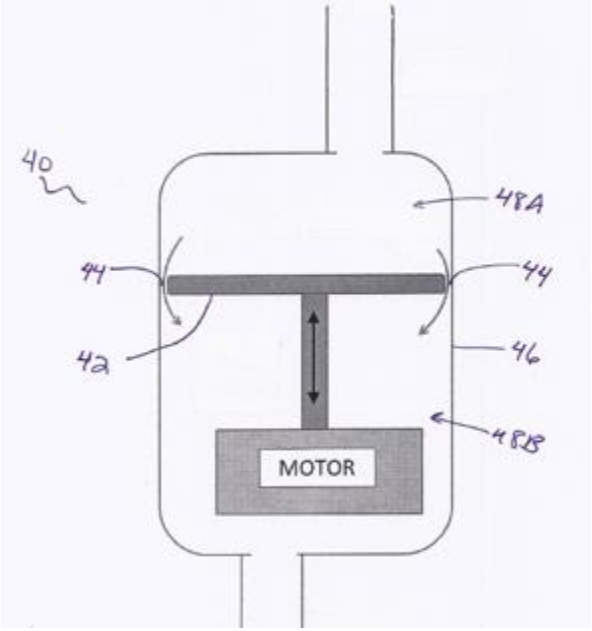


C-Pulse II – Important IP progress

METHODS, SYSTEMS, AND DEVICES RELATING TO A FAIL-SAFE PUMP FOR A HEART ASSIST DEVICE

Detailed Description

[001] The various embodiments disclosed herein relate to pumps for use in various medical device systems, including, for example, mechanical heart assist device systems.



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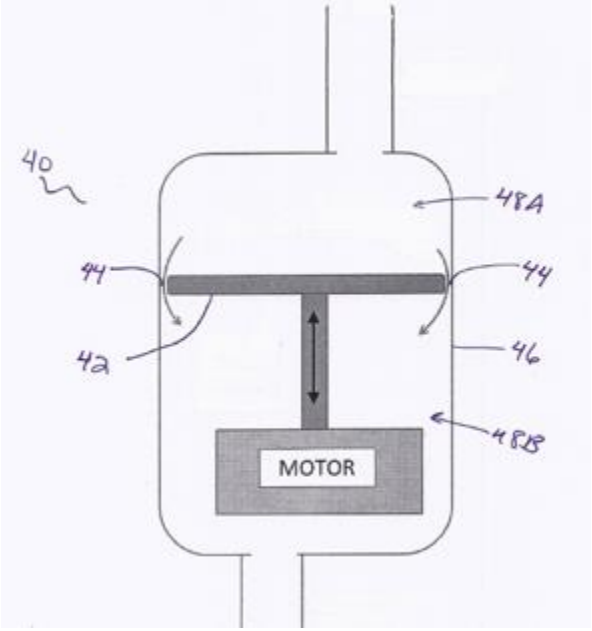
So no need for an implantable battery



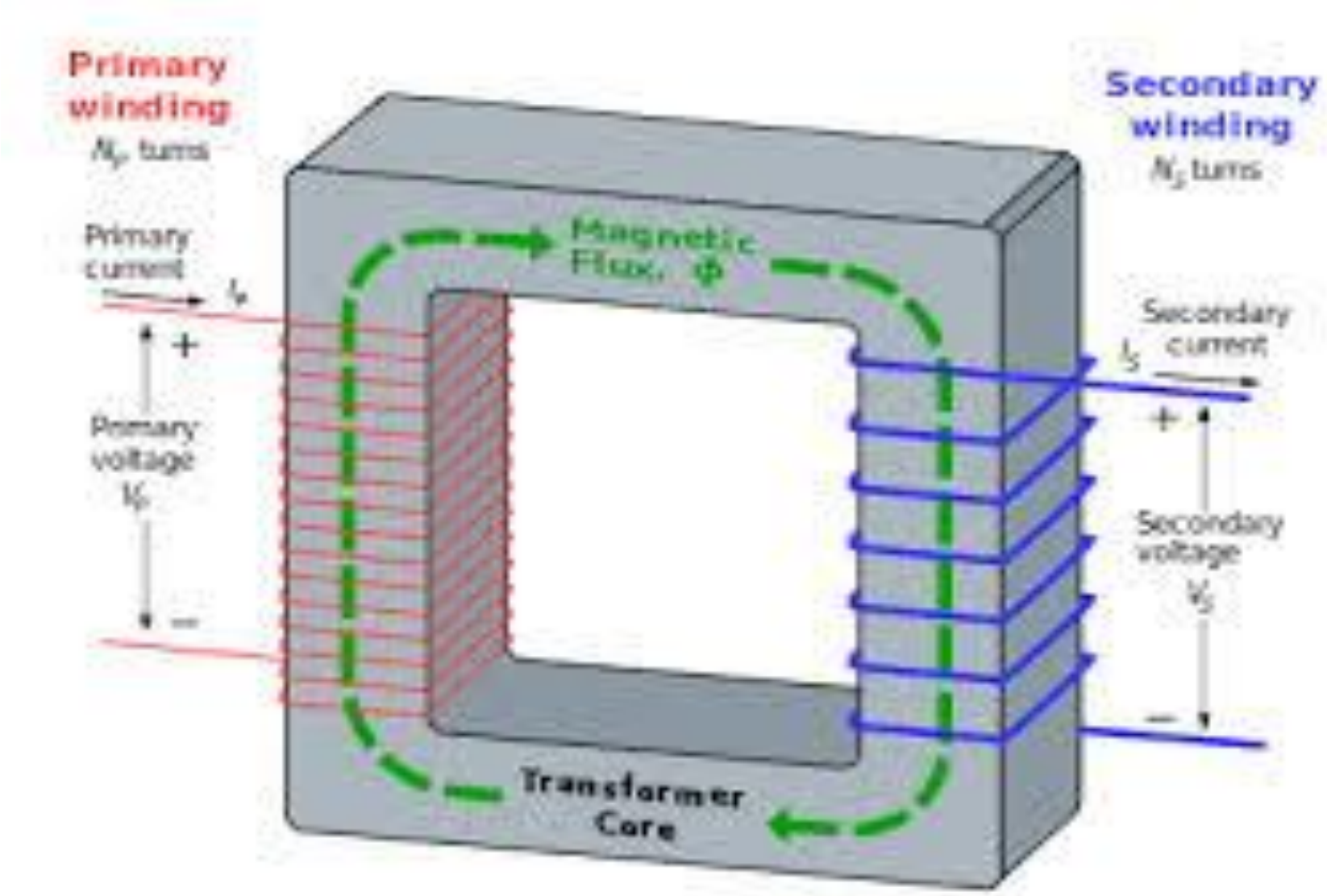
How are we going to power it?

Trans-cutaneous Energy Transfer System (TETS)

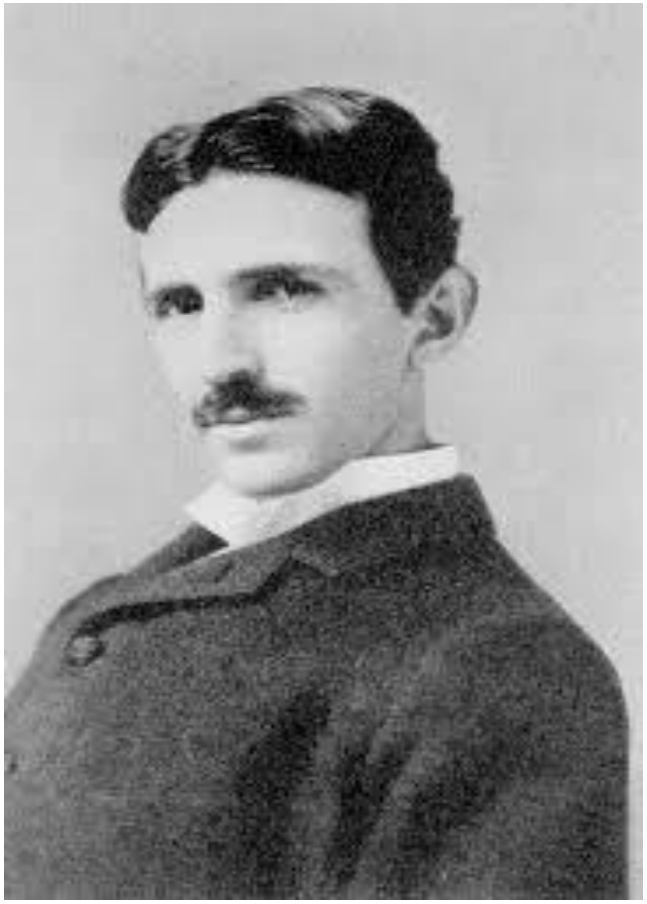
- DC battery pack outside the body
- DC current is put through an oscillator to make AC
- AC current energizes external coil (1^{o}) to generate an oscillating magnetic field
- Oscillating magnetic field goes through the skin
- Oscillating magnetic field is picked up by a tuned internal coil (2^{o}) resulting in induction of AC current
- AC current rectified into DC used to run the internal device

Standard transformer

Inductive coupling through an air-gap



Nikola Tesla



July 10, 1856 – January 7, 1943

Minnetronix

Leaders in Transcutaneous Energy Transfer Systems (TETS)

Newest systems are:

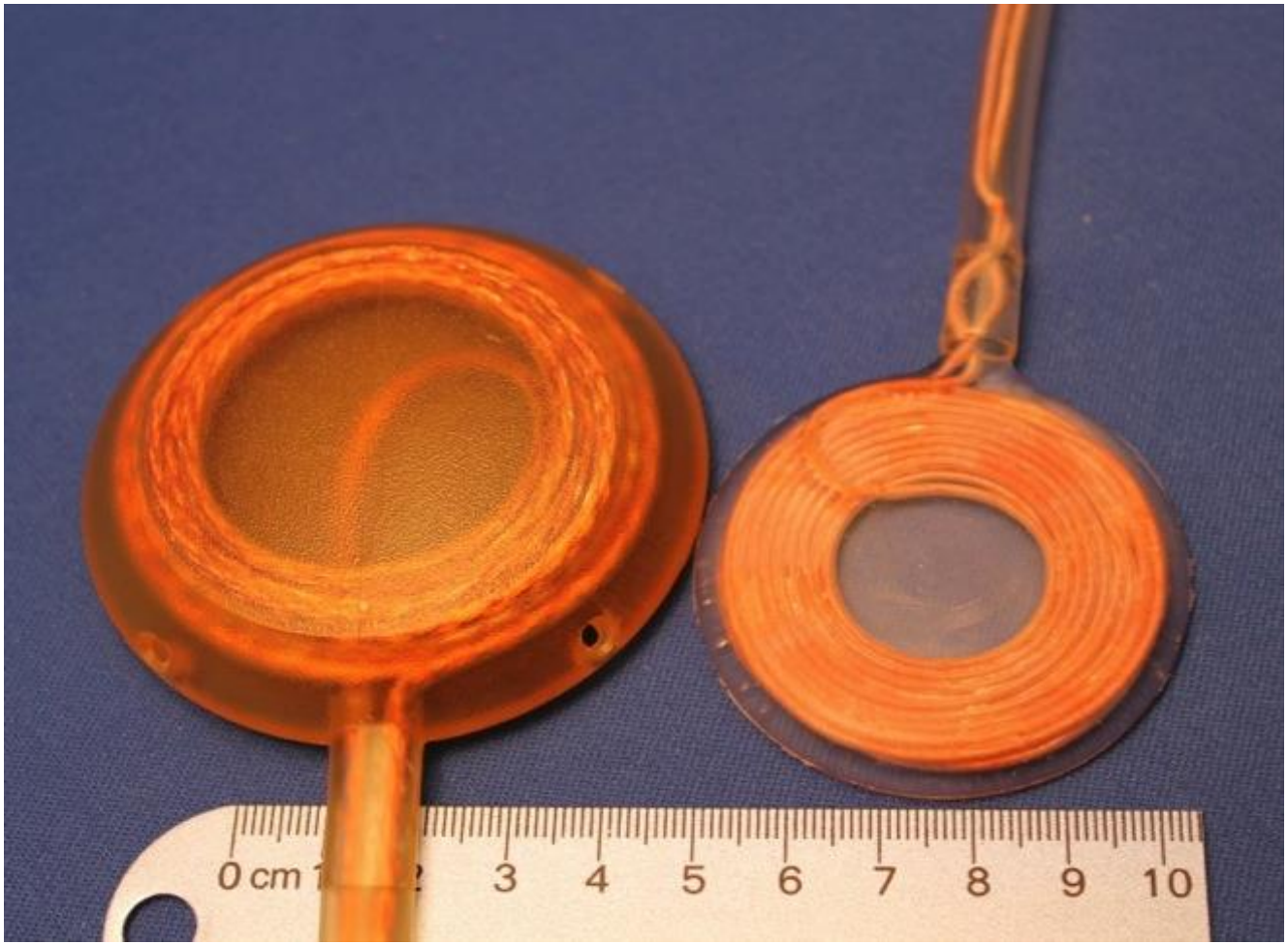
- Smaller size so easier to implant
- More energy efficient so improved battery life
- More tolerant of geometric misalignment
- Newer iterations avoid previous challenges associated with thermal injury to the skin

Minnetronix

Leaders in Transcutaneous Energy Transfer Systems (TETS)

Minnetronix

Improvement in TETS component geometry and function



Where are we going to test it?


TEXAS HEART INSTITUTE
at St. Luke's Episcopal Hospital

THI Cardiovascular Research Lab ICU

nonclinical and preclinical safety testing are required by the global regulations prior to human trials

Surgical Implant and system integration

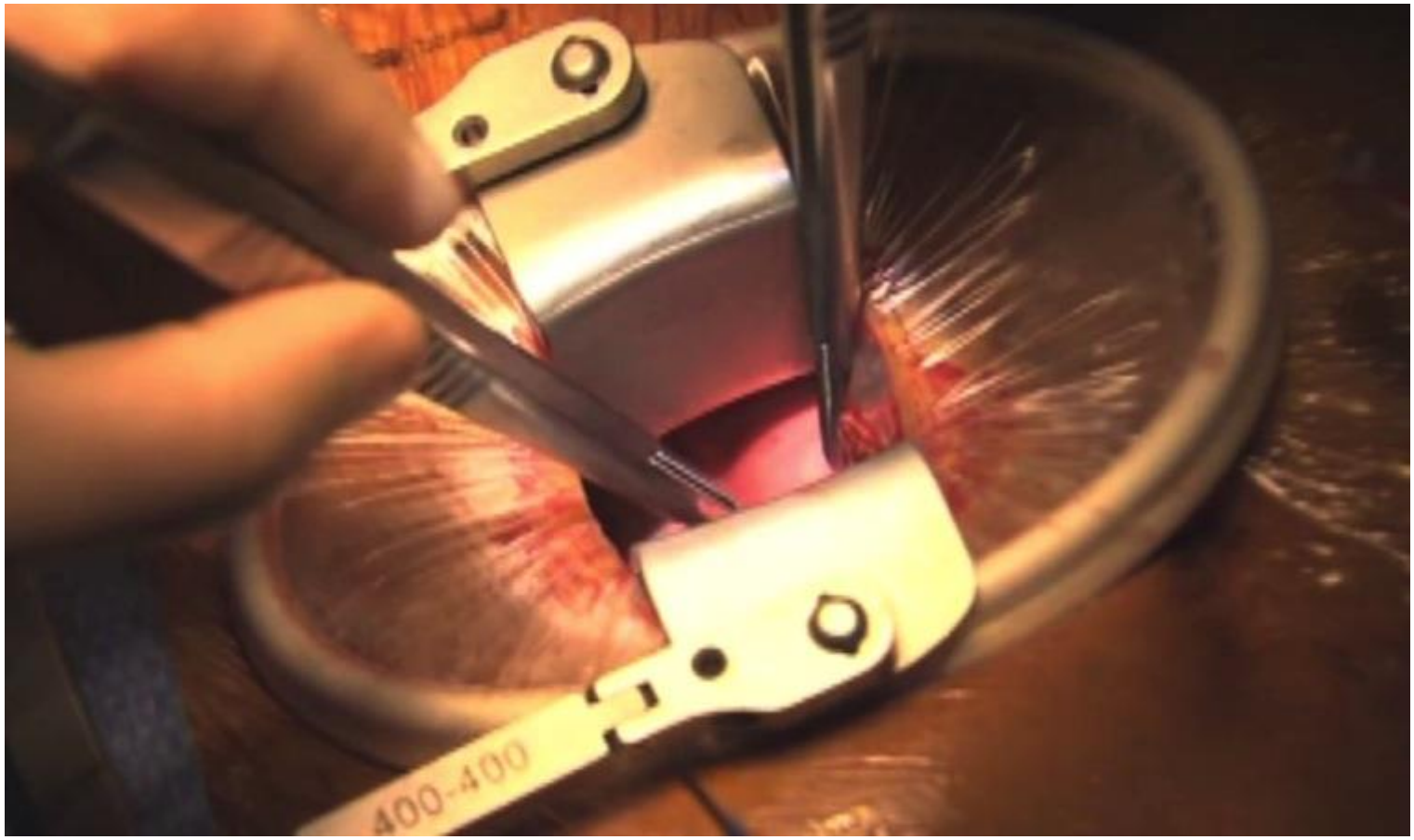
- THI's Cardiovascular Research Lab
- One of the premiere large animal cardiovascular research lab in the world
- Domain dominance in development and implementation of heart failure technology
- Successful acute system implantation (first generation)

Minimally Invasive Implantation

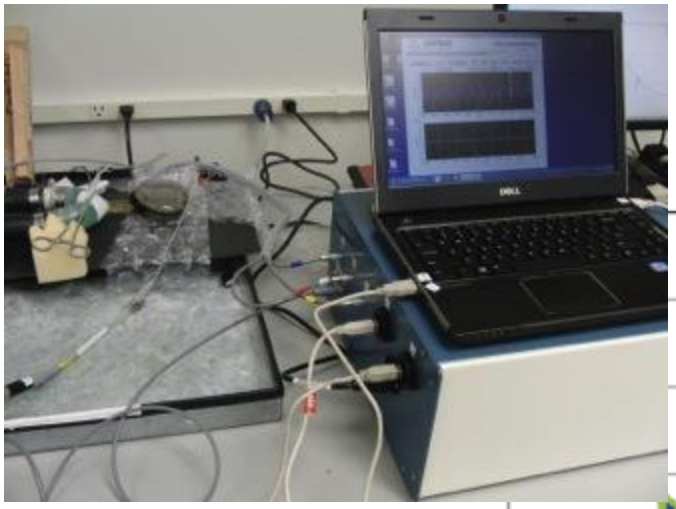
Small incision

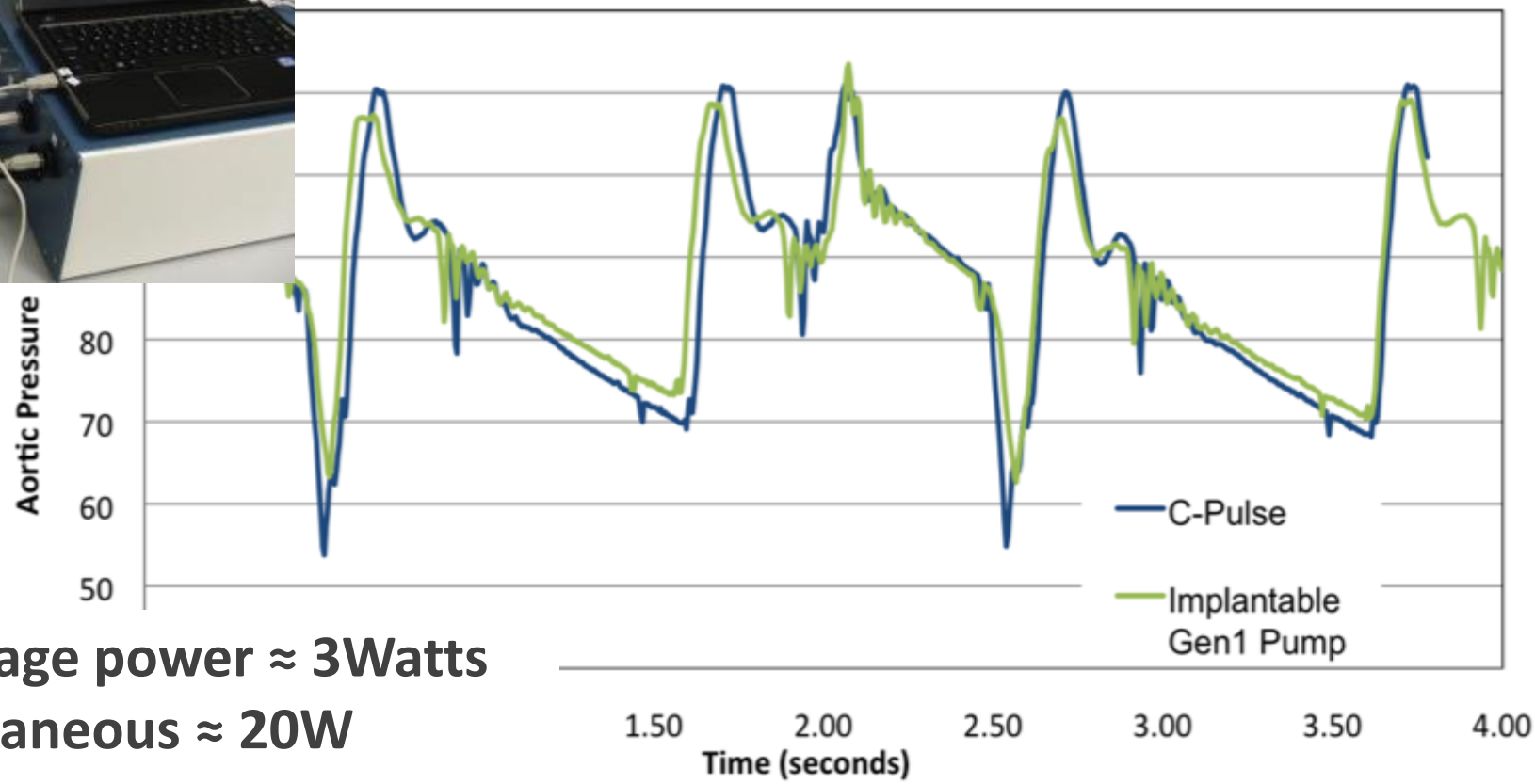
Sternal-sparing

No cardiopulmonary bypass



Recent Progress -Bench-Top Tests, CPII versus CPI





Typical Average power ≈ 3Watts

Peak Instantaneous ≈ 20W

Recent Acute animals (x2)

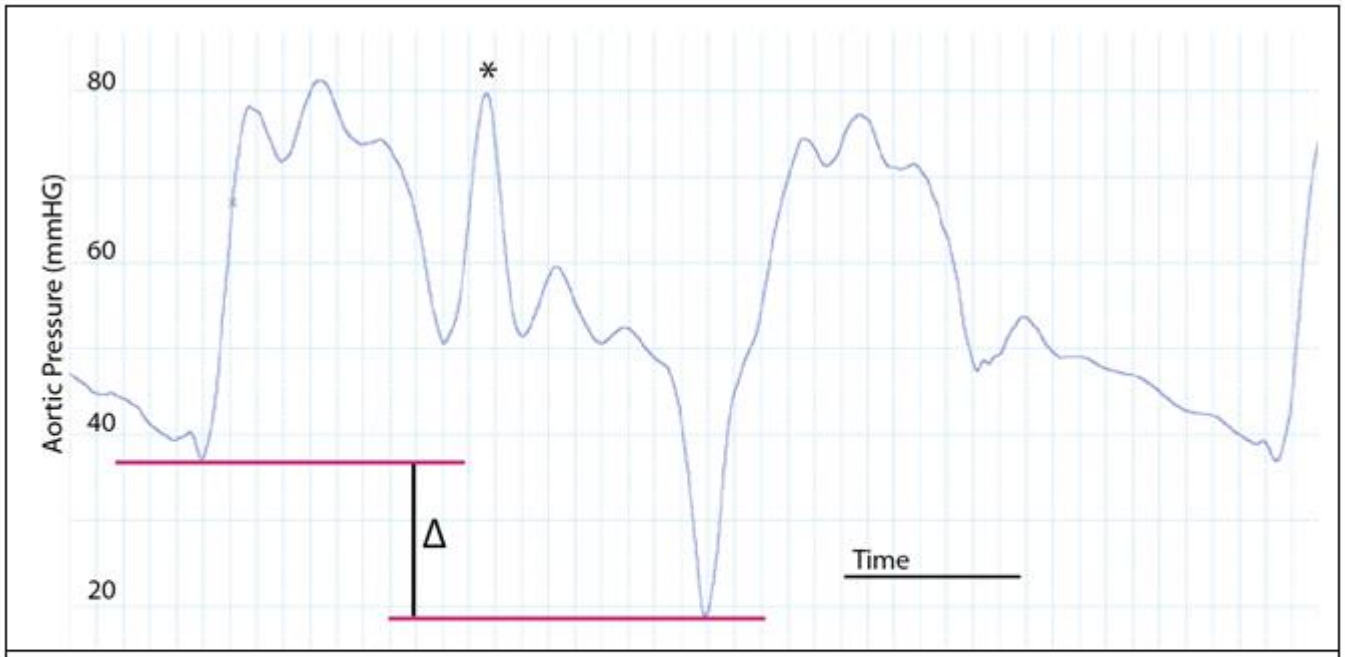
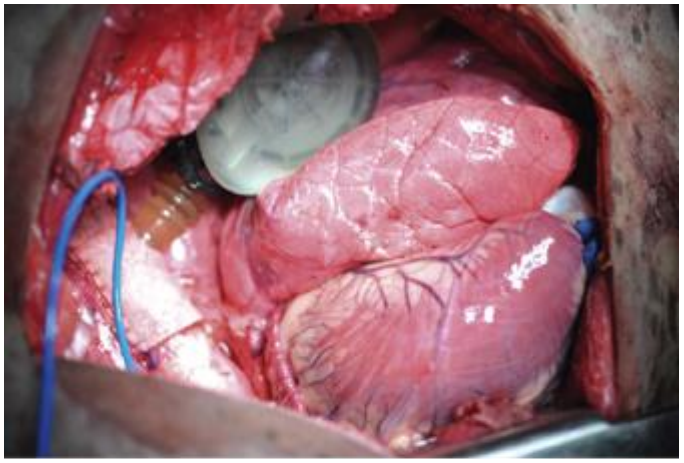
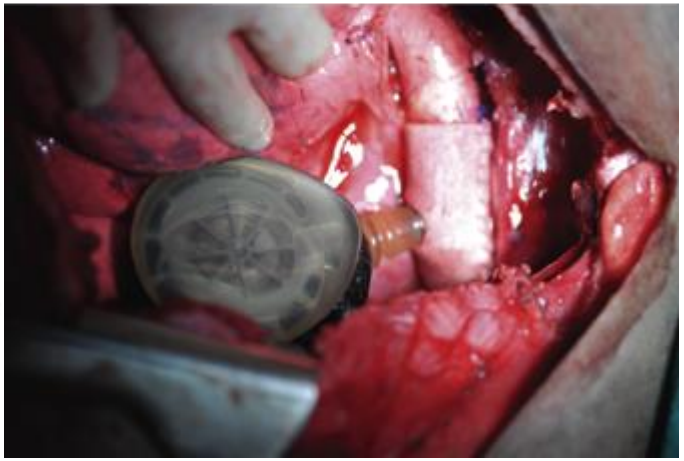
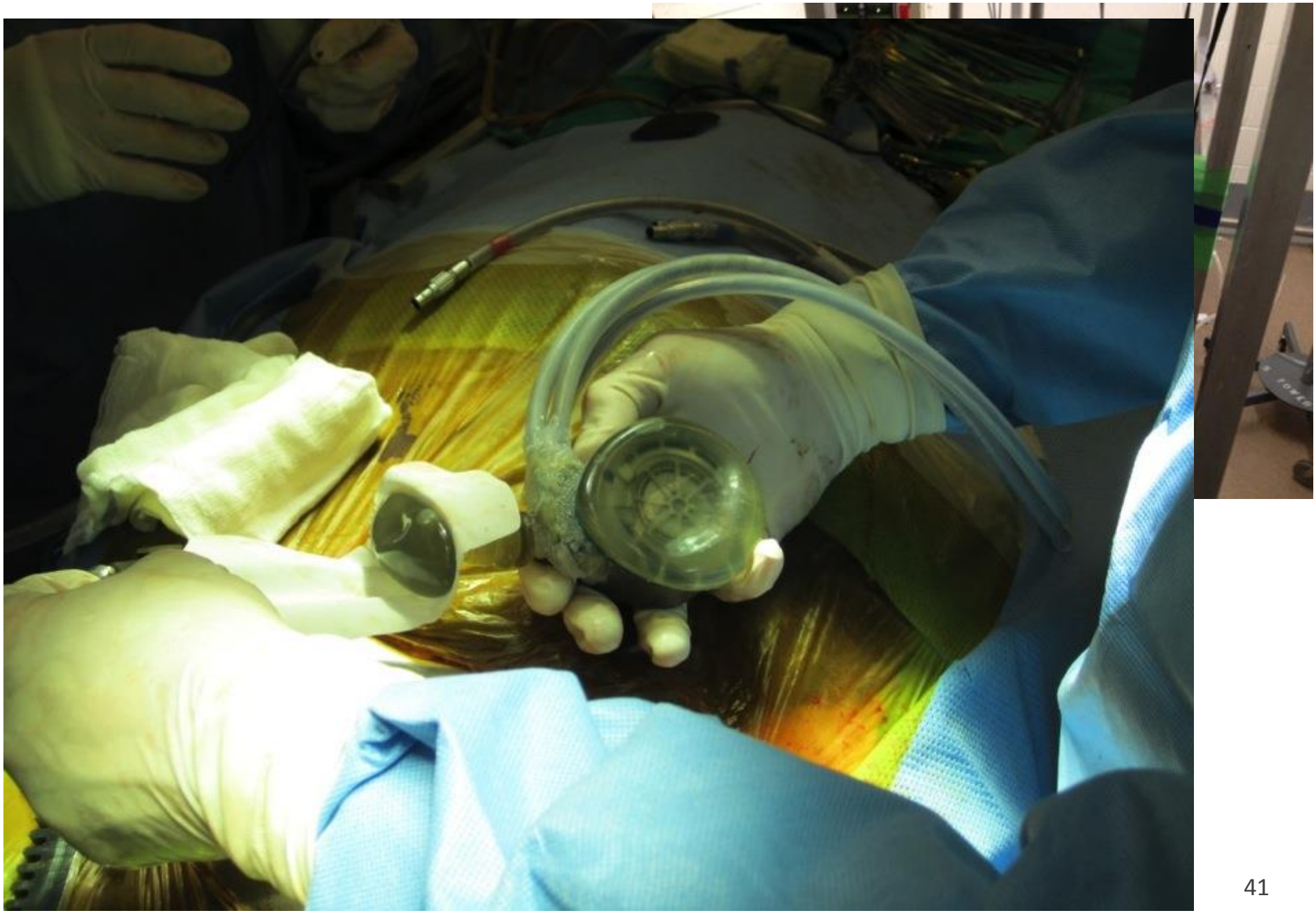
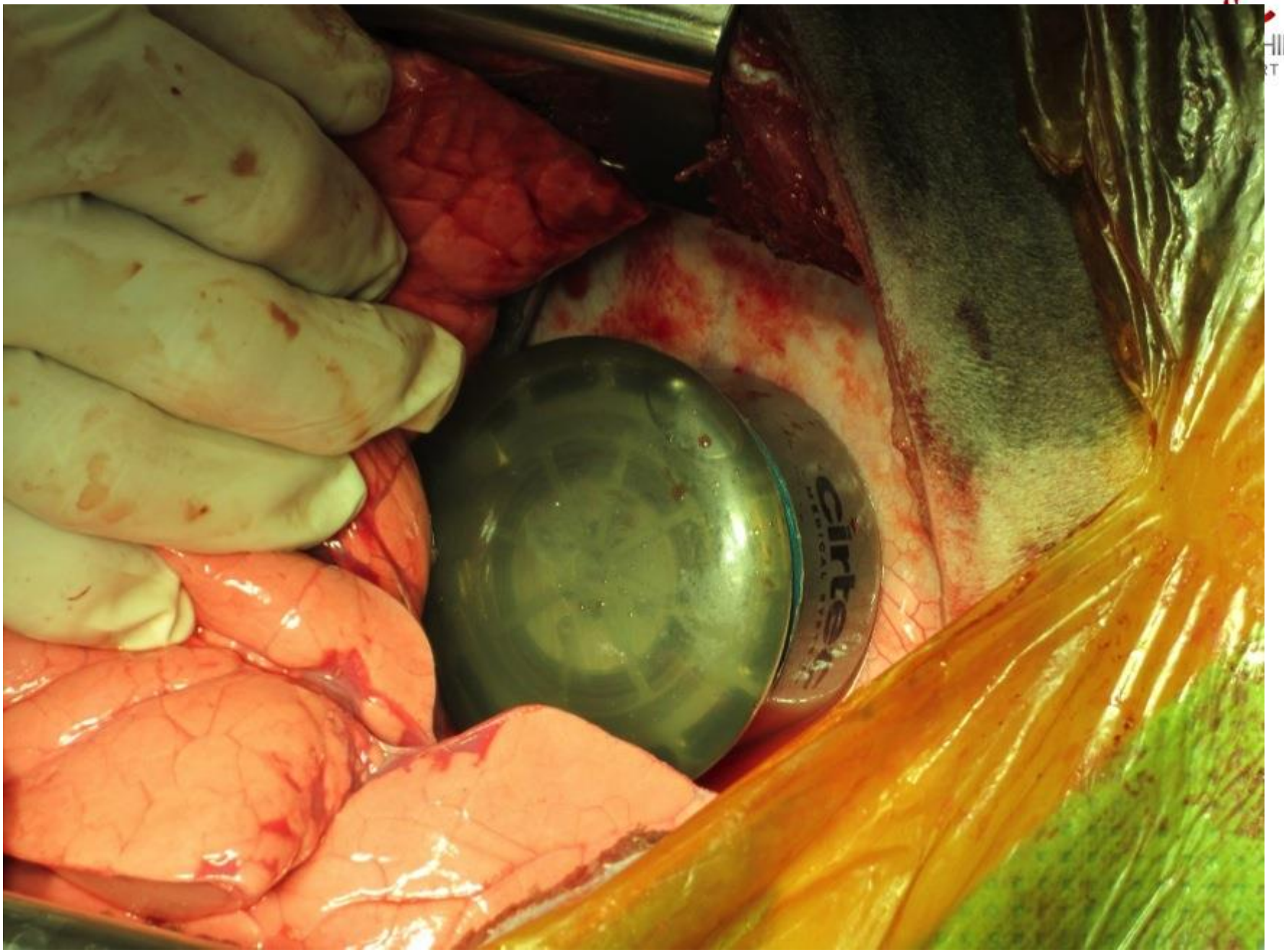


Figure 11. Hemodynamic performance of the CP2-Gen1 assembly operating in 1:2 mode during an acute bovine trial. Trace shows clear diastolic augmentation (*) and subsequent reduction in end diastolic pressure (Δ) of >15mmHg compared to the adjacent non-counterpulsated cycle.





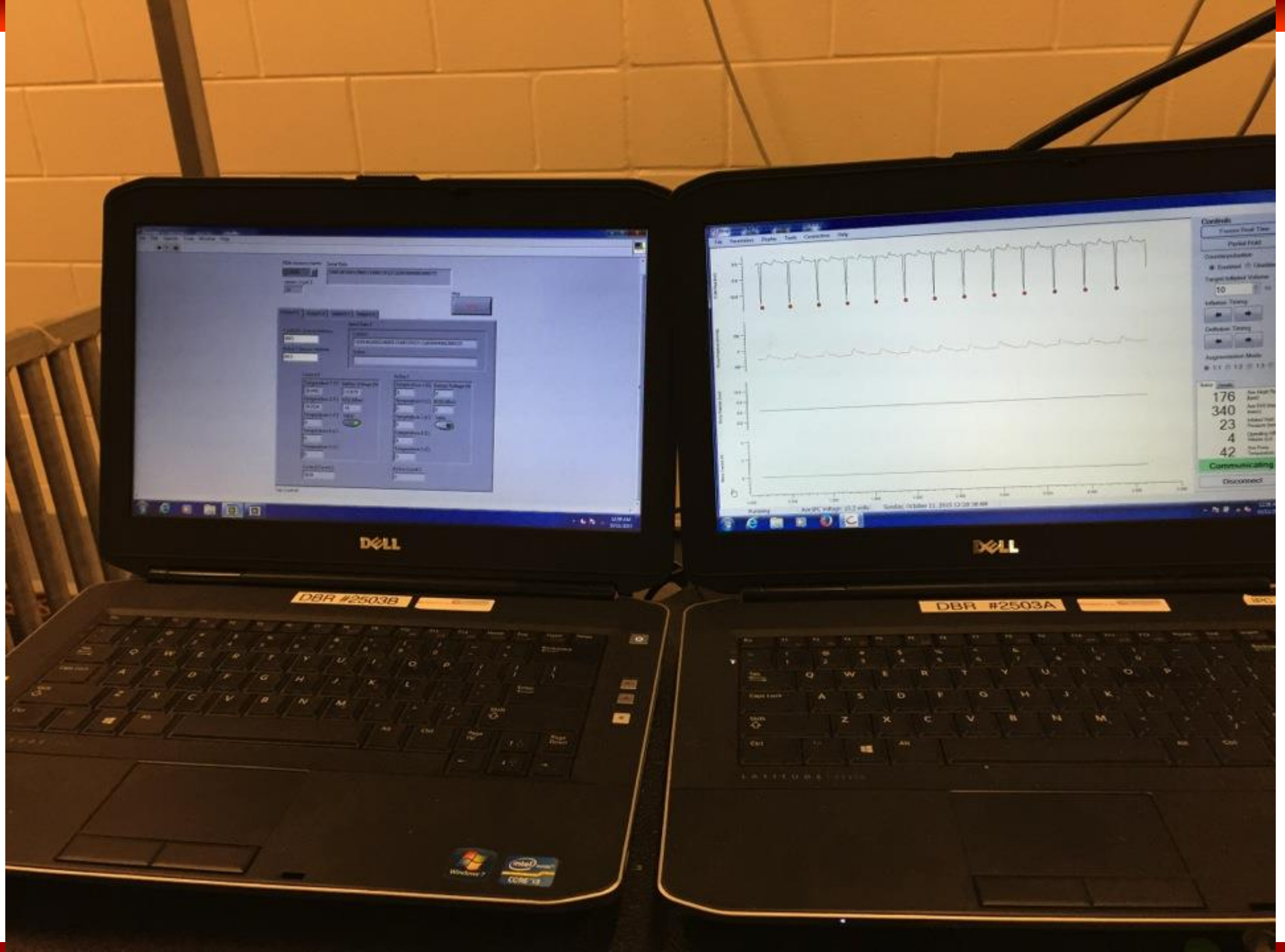





"But still try for who knows what is possible!"
Michael Faraday
FARADAY
B-1962


B-1950
EINSTEIN
Animal ID
B 1950 1503
Species
Bovine
Protocol Number
2013-19
Surgery
4B
Gender
Male
Female
DOA
DOB
10/1/14


B-1950
EINSTEIN
4


DELL
DBR #2503B
DELL
DBR #2503A
176
340
23
4
42
Communicating
Disconnect

In summary…

- The SUNSHINE HEART C-Pulse II has the potential to be the first completely self-contained therapy for heart failure since the bi-ventricular pacer
- Lack of blood contact and non-obligatory feature make it the most likely candidate to leverage TETS in a mechanical circulatory assist device
- Pump innovation has facilitated development of a novel technology, avoiding the safety and regulatory risks of an implantable battery
- The system is well suited for implantation off-pump through a small sternal sparing incision, making it well suited for patients earlier in the course of heart failure
- Early preclinical testing suggests the design is performing as intended and within established safety parameters