UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 29, 2013**

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35312**	**68-0533453**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

12988 Valley View Road
Eden Prairie, Minnesota 55344
(Address of Principal Executive Offices) (Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

On October 22, 2013, Sunshine Heart, Inc. (***"Sunshine Heart"*** or the ***"Company"***) announced that Professor Thomas Krabatsch, Andrew Kao, M.D., F.A.C.C. and Dr. William Cohn presented the initial results from the Company's clinical study of its OPTIONS HF EU trial for the Company's C-Pulse® System. These initial results were reported at the Transcatheter Therapeutics 2013 (***"TCT"***) interventional cardiology conference, which is being held October 27th through November 1st in San Francisco, California. The announcement issued by Sunshine Heart and the presentation materials delivered by Professor Thomas Krabatsch, Andrew Kao, M.D., F.A.C.C. and Dr. William Cohn at the TCT conference are attached hereto as Exhibit 99.1, 99.2, 99.3 and 99.4 respectively. A copy of each presentation will be posted under the *Investor Relations* section of Sunshine Heart's website at *http://www.sunshineheart.com.*

Limitation of Incorporation by Reference

In accordance with General Instruction B.2. of Form 8-K, this information including Exhibits 99.1, 99.2, 99.3 and 99.4, is furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Current Report on Form 8-K will not be deemed an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release - Sunshine Heart to Provide Summary of Initial OPTIONS HF Data and Additional Clinical Updates at 2013 Transcatheter Cardiovascular Therapeutics Analyst Event
99.2	Presentation - Professor Thomas Krabatsch, Director of Mechanical Circulatory Support at the German Heart Institute, Berlin
99.3	Presentation - Andrew Kao, M.D., F.A.C.C., Associate Professor of Medicine, University of Missouri-Kansas City
99.4	Presentation - Dr. William Cohn, Director of Minimally Invasive Surgical Technology of Texas Heart Institute

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

Dated: October 29, 2013

SUNSHINE HEART, INC.

By: /S/ JEFFREY S. MATHIESEN
Name: Jeffrey S. Mathiesen
Title: Chief Financial Officer

EXHIBIT INDEX

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Sunshine Heart to Provide Summary of Initial OPTIONS HF Data and Additional Clinical Updates at 2013 Transcatheter Cardiovascular Therapeutics Analyst Event

Eden Prairie, MN: October 29, 2013: Sunshine Heart, Inc. (NASDAQ: SSH) announced today that the initial C-Pulse® System patient data of its ongoing OPTIONS HF EU trial, will be presented by Professor Thomas Krabatsch, Director of Mechanical Circulatory Support at the German Heart Institute, Berlin to the investment community at Sunshine Heart's third annual analyst breakfast event, held later this morning at 7:30 a.m. PDT at the W Hotel San Francisco. As announced on October 22, 2012, the event also includes presentations from Dr. Andrew Kao, Associate Professor of Medicine at the University of Missouri-Kansas City; as well as Dr. William Cohn, Director of Minimally Invasive Surgical Technology of Texas Heart Institute. Following the event, the presentations and audio will be available on the investor section of the Sunshine Heart website at: http://ir.sunshineheart.com/index.cfm .

Initiated in February, 2013, the OPTIONS HF study is a post-market, multi-center, prospective, open label study that will include 50 patients in up to ten European centers. The study is designed to observe clinical outcomes of heart failure patients treated with the C-Pulse system concurrent with the Company's COUNTER HF™ US pivotal trial. The primary endpoint is identical to the COUNTER HF trial as it evaluates rate of re-hospitalization due to worsening heart failure and heart failure related death.

On October 28th, Professor Krabatsch, with cooperation from Dr. Holger Hotz at Cardio Centrum Berlin, presented initial OPTIONS HF study data on patients implanted at the German Heart Center, Berlin at the 2013 TCT conference as part of Session III: LVAD's for "Less Sick Patients". Data presented included 15 cumulative days of C-Pulse therapy across five individual patients, four of which remain on C-Pulse therapy. An additional two patients have been implanted at other centers and are not included in this presentation. As presented by Dr. Krabatsch, the four patients on C-Pulse therapy range from 51 to 63 years of age, and include three patients classified as NYHA Class III and one classified as NYHA ambulatory Class IV. All four patients are currently at home with the device. Early results indicate that surgical implantation without cardiopulmonary bypass was successful in all patients with no reports of stroke, myocardial infarction, major bleeding or infection (exit site or otherwise) due to the device. In addition, there have been no re-hospitalizations due to worsening heart failure or heart failure related death, which is the primary endpoint in the U.S. COUNTER HF trial. High compliance (>90%) has been reported thus far, with patients disconnecting only for battery charge or showering. In addition, patients and physicians report high satisfaction with the device. Dr. Krabatsch also summarized results from two specific trial patients, presented earlier this year at ESAIO in Scotland on September 13, 2013. Data included encouraging improvement across both patients within left and right ventricle ejection fraction, and one patient reported improving from NYHA Class III heart failure at baseline to NYHA Class II after just six weeks on the device. The same patient reported a 74% increase in observed six minute walk score at six weeks, improving to 418m from 240m at baseline. Further information will be available during the Company's third quarter earnings call on November 11th at 9:00 a.m. EST.

Dr. Kao's presentation provides data from a single center; St. Luke's Mid America Heart Institute. The Company had previously announced that two patients from the U.S. North American Feasibility study had been fully weaned from the device. Dr. Kao's presentation profiles three additional patients implanted with the C-Pulse device from the feasibility trial as well. Two of the patients have now been successfully weaned from the device following significant improvements in both heart failure NYHA classification, ejection fractions, and heart failure related symptoms, while a third patient is in the process of being weaned. Patient profiles include C-Pulse usage and key heart failure metrics along the progression of treatment, as well as individual lessons learned from each patient. The Company will not allow weaning in the U.S. COUNTER HF trial to prevent any impact on the clinical results.

Dr. William Cohn's presentation unveils the most recent advancements in the developing C-Pulse fully-implantable system, including system design, capabilities and upcoming test plans. The device will be non-blood contacting and non-obligatory, providing the patient with active inflation without the necessity for an implanted battery. In addition, the system will also eliminate the exit site, as well as percutaneous lead and associated infection risks.

Sunshine Heart will release its third quarter operating results and clinical trial update before the market open on November 11, 2013. Subsequent to the quarterly release, the Company will host a conference call at 9:00 a.m. EST.

About the C-Pulse® Heart Assist System

The C-Pulse Heart Assist System, or C-Pulse System, an investigational device in the United States, Canada and countries that do not recognize the CE mark approval, utilizes the scientific principles of intra-aortic balloon counterpulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Combined, these potential benefits may help sustain the patient's current condition or, in some cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as left ventricular assist devices (LVADs), artificial hearts or transplants. It may also provide relief from the symptoms of Class III and ambulatory Class IV heart failure and improve quality of life and cardiac function. Based on the results from our feasibility trial, we also believe that some patients treated with our C-Pulse System will be able to stop using the device due to sustained improvement in their condition as a result of the therapy.

Caution: Investigational device, limited by Federal (or United States) Law to Investigational use.

About Sunshine® Heart

Sunshine Heart, Inc. is a medical device company focused on developing, manufacturing and commercializing the C-Pulse System for treatment of Class III and ambulatory Class IV heart failure. Sunshine Heart has completed an approved U.S. Food and Drug Administration (FDA) feasibility clinical trial of the C-Pulse System and presented the results in November 2011. In March 2012, the FDA notified the Company that it could move forward with an investigational device exemption (IDE) application. Sunshine Heart received unconditional approval from the FDA in November 2012 to initiate its pivotal trial. In July 2012 Sunshine Heart received CE Mark approval for its C-Pulse System in Europe. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with a wholly owned subsidiary in Australia. The Company has been listed on the NASDAQ Capital Market since February 2012.

Forward-Looking Statements

Certain statements in this release are forward-looking statements that are based on management's beliefs, assumptions, expectations, and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including, without limitation, future clinical trial activities and results including patient enrollment in trials. These forward-looking statements are subject to numerous risks and uncertainties, including, without limitation, the possibility that our clinical trials do not meet their enrollment goals, meet their endpoints or otherwise fail, that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the possibility that we may be unable to raise the funds necessary for the development and commercialization of our products, that we may not be able to commercialize our products successfully in the European Union and the other risk factors described under the caption "Risk Factors" and elsewhere in our filings with the Securities and Exchange Commission. You should not place undue reliance on forward-looking statements because they speak only as of the date when made and may turn out to be inaccurate. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

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Source: Sunshine Heart

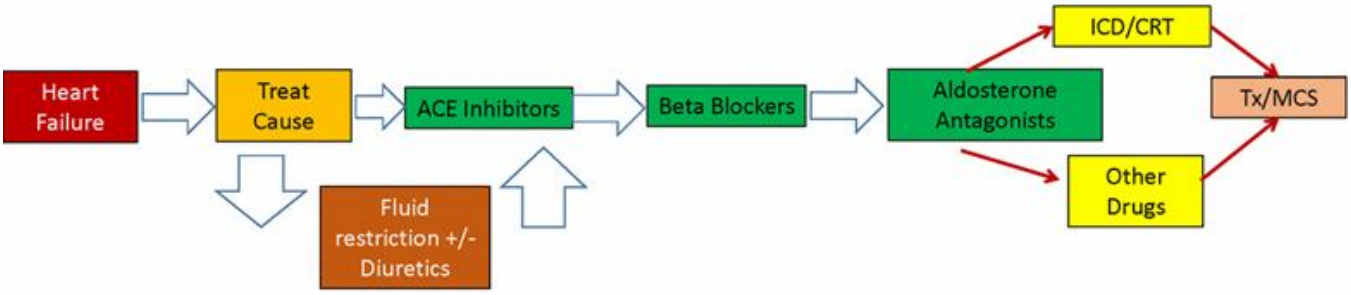
Cardio Centrum Berlin

DEUTSCHES HERZZENTRUM BERLIN

Disclosure Statement of Financial Interest

I, Thomas Krabatsch, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Modern management of systolic heart failure with reduced EF



INTERMACS 7 6 5 4 3 2 1

European Society for Cardiology

2012 Guidelines for Acute and Chronic Heart Failure

Table of Contents : Full Text (ESC Clinical Practice Guidelines)

- Preamble
- Introduction
- Definition and diagnosis
- The role of cardiac imaging in the evaluation of patients with suspected or confirmed heart failure
- Other investigations
- Devices and surgery
- Prognosis
- Pharmacological treatment of HF-REF (systolic heart failure)
- Pharmacological treatment of HF-PEF (diastolic heart failure)
- Non surgical device treatment of HF-REF (systolic heart failure)
- Arrhythmias, bradycardia and atrioventricular block in patients with HF-REF and HF-PEF
- Importance and management of other comorbidity in HF-REF and HF-PEF
- Acute heart fialure
- Coronary revascularization and surgery, including valve surgery, **ventricular assist devices** and transplantation
- Holistic managment, including exercise training and mutidisciplinary management programmes, patient monotoring and palliative care

NYHA Classification

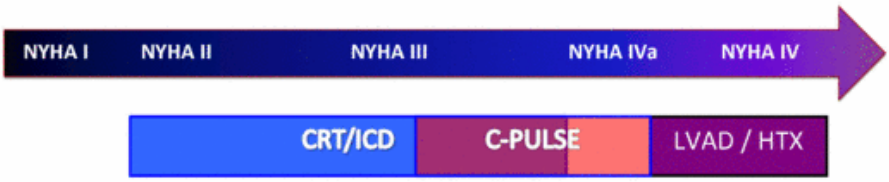
Class I— No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or angina.
Class II—Slight limitation of physical activity. Patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or angina.
Class III—Marked limitation of physical activity. Patients are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or angina.
Class IV—Inability to carry on any physical activity without discomfort. Symptoms of heart failure or the angina syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Device treatment options for patients with moderate to severe heart failure

- 3.5 million European patients in NYHA class III[1]
- 1 million European patients in NYHA class III with CRT[1]
- Despite OMT and current treatments all-cause mortality rate for advanced HF with reduced EF at 3 years remains ~30%
- Indicating the need to continue seeking new treatment options[2]

1. SHAPE (Study Group on Heart Failure and Perception in Europe) & The World Heart Failure Society
2. Loh, John C. et al. (2013) Temporal Trends in Treatment and Outcomes for Advanced Heart Failure With Reduced Ejection Fraction From 1993 -2010: Findings From a University Referral Center. Circulation Heart Failure, May 2013. 411-419.

Addressing the existing treatment need

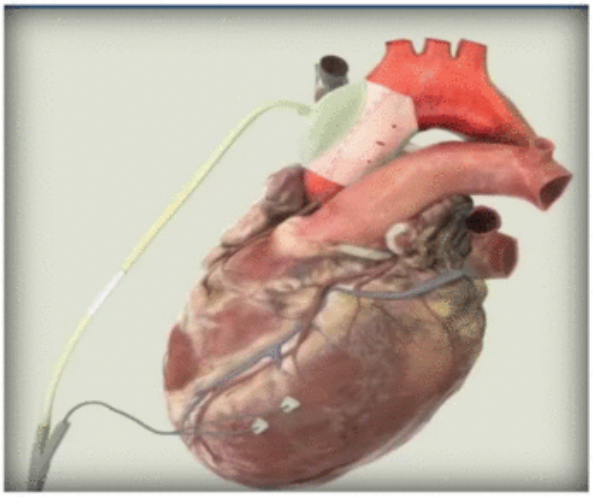


- For patients that need more than optimal medical therapy
- C-Pulse®, a device designed to provide symptomatic relief with the potential to halt disease progression

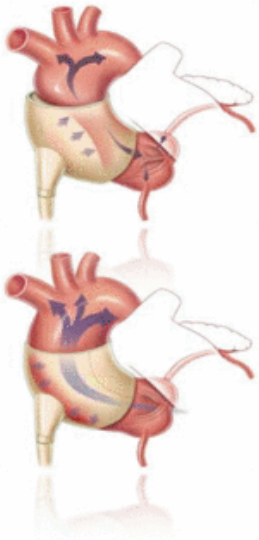
CE 0086

US Pivotal Counter HF™ Trial currently enrolling.
CAUTION: C-Pulse is an Investigational device. The device is limited by Federal (or United States) Law to Investigational use only.

Ambulatory Extra-Aortic Counterpulsation



C-Pulse System



C-Pulse® System

C-Pulse® Counterpulsation Therapy

C-Pulse System:

1. Placed **outside** the bloodstream (no anticoag., no hemolysis, no vWD, no thrombosis)
2. Allows patients the ability to **disconnect** for short periods of time (e.g. for personal hygiene)
3. May be placed minimally invasively

C-Pulse System is designed to:

1. Increase coronary blood flow
2. Decrease afterload
3. Increase cardiac function

Options HF C-Pulse® System European Multicenter Study

Multi-center, prospective, open label observational study, 50 Patients, 15 European Centers

Study objective: The study is designed to observe the clinical outcomes of heart failure patients treated with C-Pulse® System according to the approved indications and contraindications.

Regulatory status: CE Mark

Inclusion Criteria = intended use

According to the CE mark authorization, patients with the following conditions can be included:

- Patient is 18 years or older
- Patients with moderate to severe ambulatory heart failure [American College of Cardiology/American Heart Association (ACC/AHA) Stage C; NYHA Class III/IV ambulatory], who are refractory to optimal medical therapy.
- Patients who are non-responders to CRT pacemaker therapy
- Patient has signed and dated the investigation informed consent form

Options HF C-Pulse® System European Multicenter Study

Exclusion Criteria (Contraindications)

According to the CE mark authorization, patients with the following conditions (contraindications) have to be excluded:

- Evidence of significant ascending aortic calcification
- Moderate or severe atherosclerotic aortic disease
- Ascending aorto-coronary artery bypass grafts
- Any history of aortic dissection
- Patient has severe mitral valve incompetence, grade 4+
- Patient has moderate to severe aortic valve incompetence, grade 2 - 4+
- Patient has systolic blood pressure less than 90 or greater than 140mmHg

Investigated parameters

- Quality of life (Kansas City)
- 6-min-walk test
- Left ventricular ejection fraction
- Adverse events

The Berlin Referral System

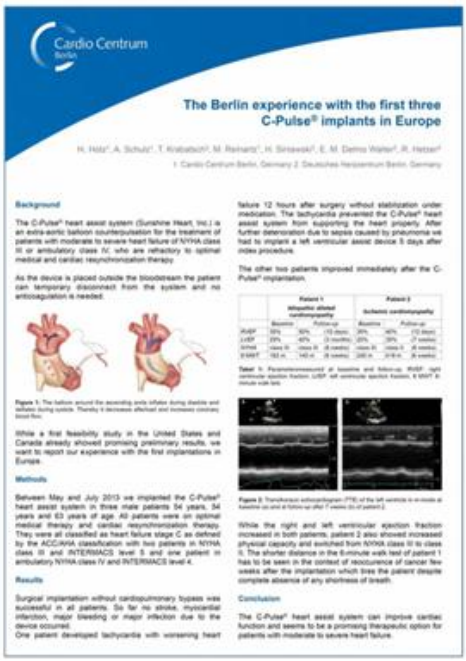
Cardiologists in practice
- Identify potential patient
- Long-term follow-up

Cardio Centrum Berlin
Outpatient Heart Clinic
Options HF Study Site
- Screening
- Prepare pt. for implantation
- Follow-Ups

DHZB
Experienced VAD center
- Implant procedure
- Intensive care

DHZB C-Pulse® Experience

- 4 male patients implanted
- 54 years, 54 years, 63 and 51 years of age
- All classified ACC/AHA stage C
- All patients on OMT
- 3 patients - NYHA class III and INTERMACS level 5
- 1 patient - NYHA ambulatory class IV and INTERMACS level 4



Cardio Centrum Berlin

The Berlin experience with the first three C-Pulse® implants in Europe

H. Holz[1], A. Schulz[1], T. Krabatsch[2], M. Reinartz[1], H. Siniawski[2], E. M. Dalmo Walter[2], R. Hetzer[2]

1 Cardio Centrum Berlin, Germany 2 Deutsches Herzzentrum Berlin, Germany

Background

The C-Pulse® heart assist system (Sunshine Heart, Inc.) is an extra-aortic balloon counterpulsation for the treatment of patients with moderate to severe heart failure of NYHA class III or ambulatory class IV, who are refractory to optimal medical and cardiac resynchronization therapy.

As the device is placed outside the bloodstream the patient can temporary disconnect from the system and no anticoagulation is needed.

Figure 1: The balloon around the ascending aorta inflates during diastole and deflates during systole. Thereby it decreases afterload and increases coronary blood flow.

While a first feasibility study in the United States and Canada already showed promising preliminary results, we want to report our experience with the first implantations in Europe.

Methods

Between May and July 2013 we implanted the C-Pulse® heart assist system in three male patients 54 years, 54 years and 63 years of age. All patients were on optimal medical therapy and cardiac resynchronization therapy. They were all classified as heart failure stage C as defined by the ACC/AHA classification with two patients in NYHA class III and INTERMACS level 5 and one patient in ambulatory NYHA class IV and INTERMACS level 4.

Results

Surgical implantation without cardiopulmonary bypass was successful in all patients. So far no stroke, myocardial infarction, major bleeding or major infection due to the device occured.
One patient developed tachycardia with worsening heart failure 12 hours after surgery without stabilization under medication. The tachycardia prevented the C-Pulse® heart assist system from supporting the heart properly. After further deterioration due to sepsis caused by pneumonia we had to implant a left ventricular assist device 5 days after index procedure.

The other two patients improved immediately after the C-Pulse® implantation.

	Patient 1 Idiopathic dilated cardiomyopathy		Patient 2 Ischemic cardiomyopathy	
	Baseline	Follow-up	Baseline	Follow-up
RVEF	30%	30%	25%	40%
LVEF	25%	40%	20%	30%
NYHA	class III	class II	class III	class II
6 MWT	182 m	140 m	240 m	418 m

Table 1: Parametermeasured at baseline and follow-up. RVEF: right ventricular ejection fraction; LVEF: left ventricular ejection fraction; 6 MWT: 6-minute walk test.

Figure 2: Transthoracic echocardiogram (TTE) of the left ventricle in 4-chamber at baseline (on site) at follow-up after 7 weeks (on x2 patient 2).

While the right and left ventricular ejection fraction increased in both patients, patient 2 also showed increased physical capacity and switched from NYHA class III to class II. The shorter distance in the 6-minute walk test of patient 1 has to be seen in the context of reoccurrence of cancer few weeks after the implantation which lives the patient despite complete absence of any shortness of breath.

Conclusion

The C-Pulse® heart assist system can improve cardiac function and seems to be a promising therapeutic option for patients with moderate to severe heart failure.

Cardio Centrum Berlin

DEUTSCHES HERZZENTRUM BERLIN

Current State: German C-Pulse® Experience

- 5 patients implanted as part of the *Options HF C-Pulse® post market clinical study*
- 415 total days of C-Pulse therapy
- 4 patients continue on C-Pulse therapy, all at home

Hospital Name	Implant Date	Patient Age at Implant	Duration of support
Berlin, Cardio Centrum	07.05.2013	63	165
Berlin, Cardio Centrum	14.06.2013	54	5
Berlin, Cardio Centrum	27.06.2013	55	114
Hannover, MHH	01.08.2013	79	79
Berlin, UKB	26.09.2013	51	23

- The second patient (implanted 14 June 2013) developed tachycardia with worsening heart failure 12 hours after surgery without stabilization under medication. Tachycardia prevented optimal C-Pulse support
- Further deterioration due to sepsis caused by pneumonia
- Implantation of a left ventricular assist device 5 days after index procedure

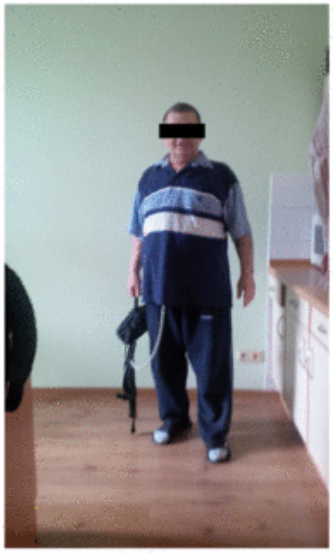
Duration of support: Dated 19 October 2013

Cardio Centrum Berlin

DEUTSCHES HERZZENTRUM BERLIN

Patients in Germany

- 420 Patient days in Europe
- No Exit Site Infections
- No re-hospitalizations due to HF
- High compliance – Only disconnect for battery change
- High satisfaction from physicians and patients



Berlin Patient - 114 days
LVEF 25 to 35%

Early Clinical Results

Berlin Patient Results Presented at ESAIO in ScotlandSeptember 13th
in cooperation with Dr. Holger Hotz from Cardio Centrum*

	Patient 1** Idiopathic dilated cardiomyopathy		Patient 3 Ischemic cardiomyopathy	
	Baseline	*Follow-up*	*Baseline*	*Follow-up*
RVEF	35%	50% (10 days)	35%	40% (12 days)
LVEF	25%	40% (3 months)	20%	35% (7 weeks)
NYHA	III	III (6 weeks)	III	II (6 weeks)
6 MHW	183 m	145 m (6 weeks)	240 m	418 m (6 weeks)

*H.Hotz[1], A. Schults[1], T. Krabatsch[2], M. Reinhartz[1], H. Siniawski[2], E.M. Delmo Walter[2], R. Hetzer[2] (2013) The Berlin experience with the first three C-Pulse® implants in Europe 1. Cardio Centrum Berlin, Germany 2. Deutsches Herzzentrum Berlin, Germany

**Reduced distance is explained due to muscular weakness and lack of motivation due to cancer diagnosis

Patient Feedback

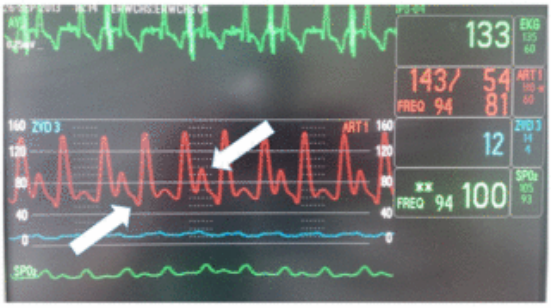
Most recent Patient Implanted at DHZB:

The patient feels excellent, he says it is "a miracle" how good he feels. He would recommend this device to everybody with similar heart problems.

He can now walk 500m to the next grocery store and do shopping and then cook for his family.

SUMMARY - Early Results

- Surgical implantation without cardiopulmonary bypass was successful in all patients
- No stroke, myocardial infarction, major bleeding or major infection due to the device
- No rehospitalisation for worsening HF



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H.Hotz[1], A. Schults[1], T. Krabatsch[2], M. Reinhartz[1], H. Siniawski[2], E.M. Delmo Walter[2], R. Hetzer[2] (2013) The Berlin experience with the first three C-Pulse® implants in Europe 1. Cardio Centrum Berlin, Germany 2. Deutsches Herzzentrum Berlin, Germany

Conclusion

- The C-Pulse® heart assist system is **easy to implant** without the need for cardiopulmonary bypass
- The C-Pulse system **can improve cardiac function**
- C-Pulse seems to be a **promising therapeutic option** for patients with moderate to severe heart failure

Can C-Pulse® Use Lead To Left Ventricular Recovery?

Andrew Kao, M.D., F.A.C.C.
Associate Professor of Medicine
University of Missouri-Kansas City

Transcatheter Cardiovascular Therapeutics
San Francisco, CA
October 29, 2013

Disclosures

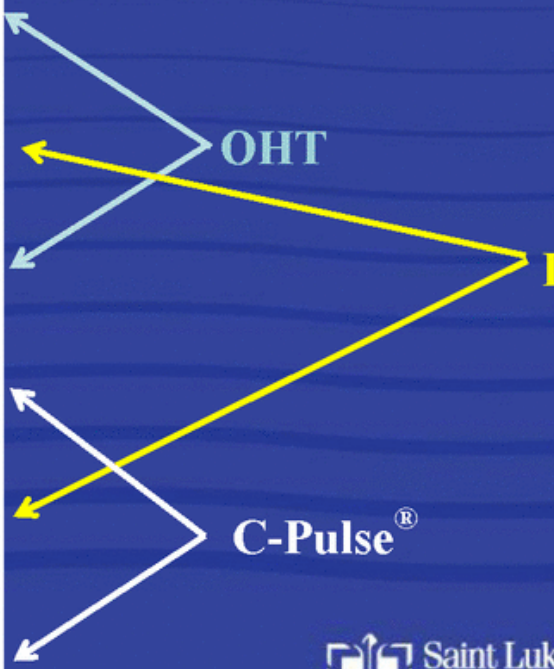
- Presentation based on data from single center experience (St. Luke's Mid America Heart Institute, Kansas City, MO) - C-Pulse® feasibility study
- Caution: C-Pulse® is an investigational device. This device is limited by federal (US) laws to investigational use only

Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

Proposed Treatment Algorithm for Advanced HF

Interagency Registry of Mechanically Assisted Circulatory Support

Profile	Description
1.	Critical cardiogenic shock
2.	Progressive decline on inotropic support
3.	Stable but inotrope dependent
4.	Resting symptoms home on oral therapy
5.	Exertion intolerant
6.	Exertion limited
7.	Advanced NYHA Class III symptoms



Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

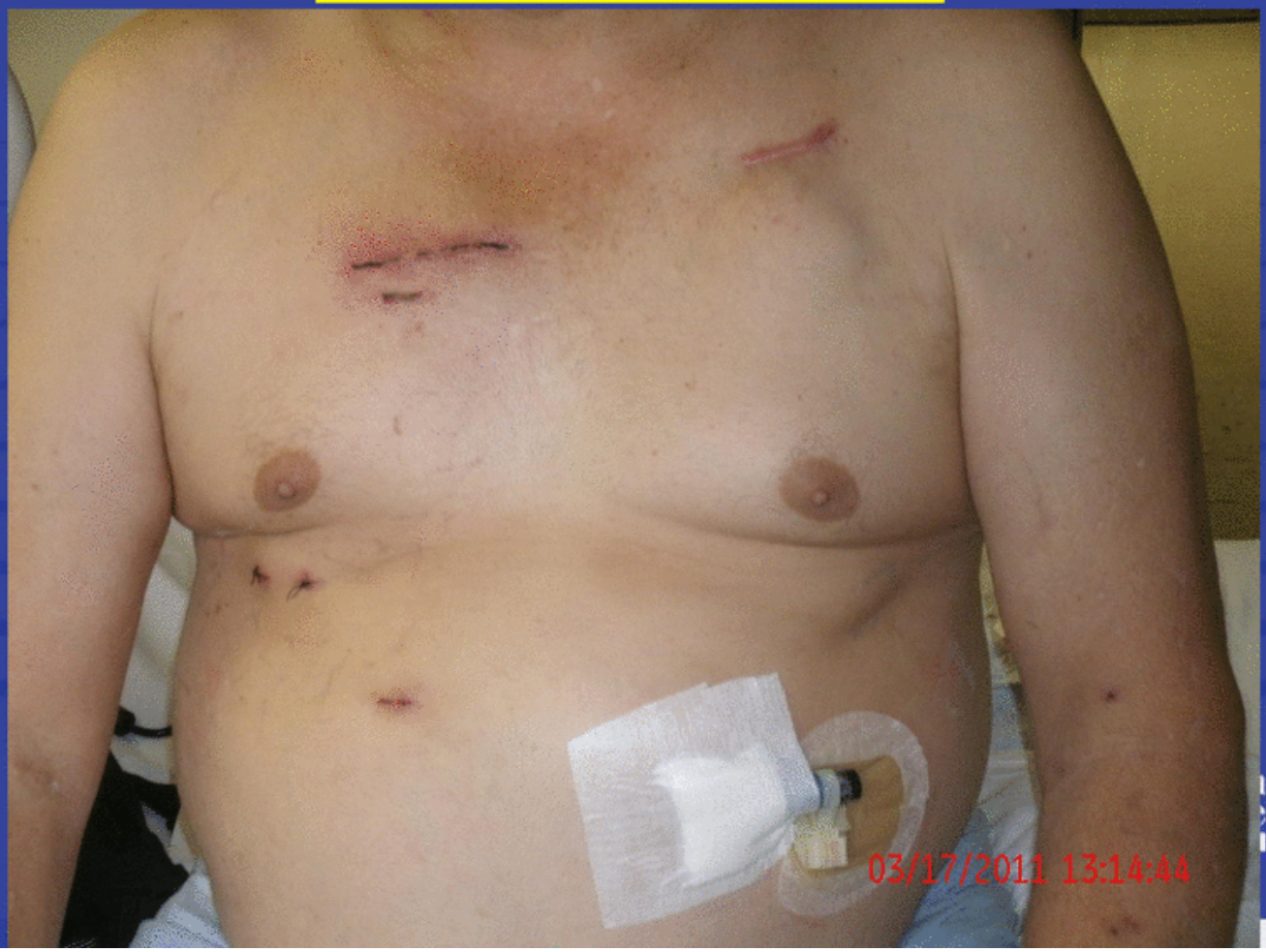
Adapted from Stevenson LW et al. J Heart Lung Transplant 2009;28:535-541

Advantages of C-Pulse® Therapy

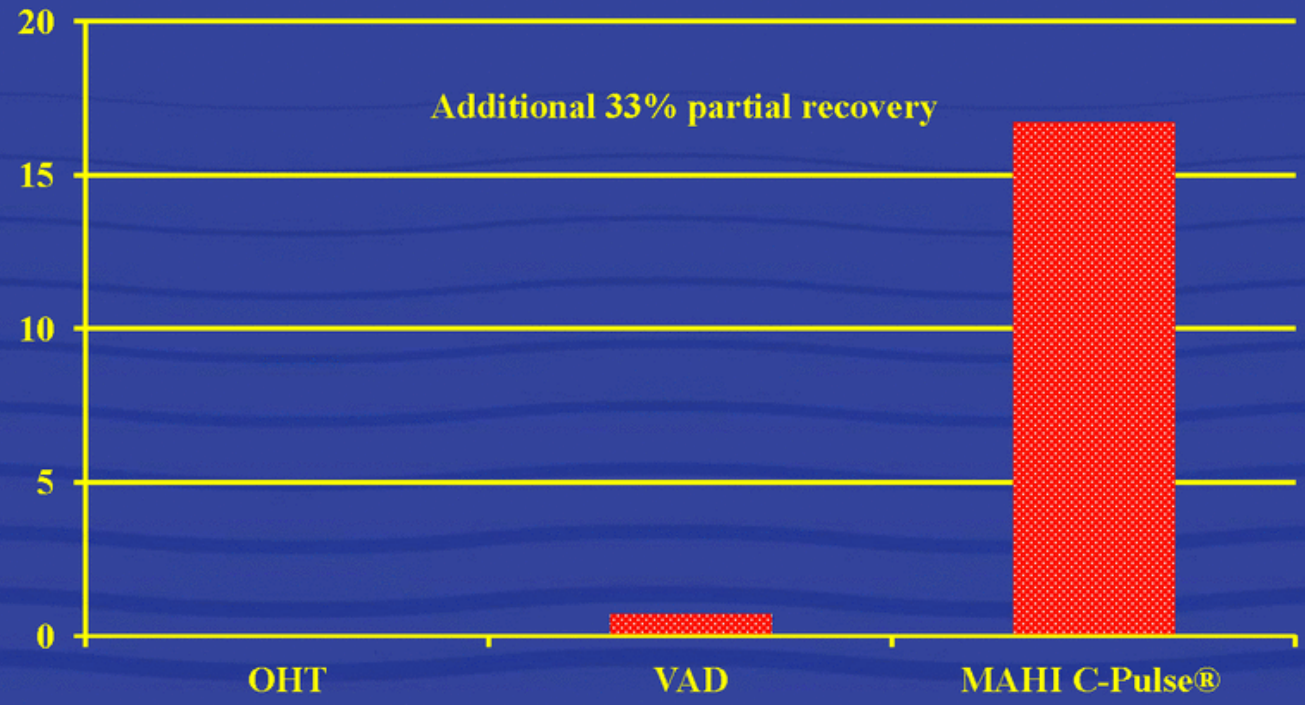
- Easy to manage – "On-Off" concept
- Cardiac assist device, not life-sustaining
- Extravascular device – no need for anticoagulation
- May be performed via mini-thoracotomy – faster recovery period

Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

C-Pulse® 1 Week



Likelihood of Ventricular Recovery



Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

INtERMACS Quarterly Statistical Report 6/13

Tales of Recovery

Saint Luke's Mid America
Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

Patient #1

- 45 yo man with 10 year history of familial dilated cardiomyopathy
- History of DVT/PE but intracranial hemorrhage from coumadin – thus not VAD candidate
- Cannot walk more than a few feet
- Prescribed oxygen by local MD
- Hemoptysis due to pulmonary edema
- Diffusely diaphoretic

Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

Patient #1

- Echo LVEF 10%
- 8/10 Right heart cath – RA 7, PA 52/23/34, PCWP 14, CO/CI 4.1/1.7
- 8/10 C-Pulse® implantation
- Discharge postop day 4
- 1 month visit – walked around air show 3-4 hours! – NYHA I since then
- 6 month RHC – RA 10, PA 35/13/23, PCWP 13, CO/CI 5.9/2.7

Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

Patient #1

- 9 months – asked for Cialis
- 1 year echo – LVEF 20%
- 2 year echo – LVEF 21%
- Preop – 140 mg Lasix a day
- 5 months postop to now – no Lasix
- 12/12 (28 months) – PIL explant
- Remains NYHA I

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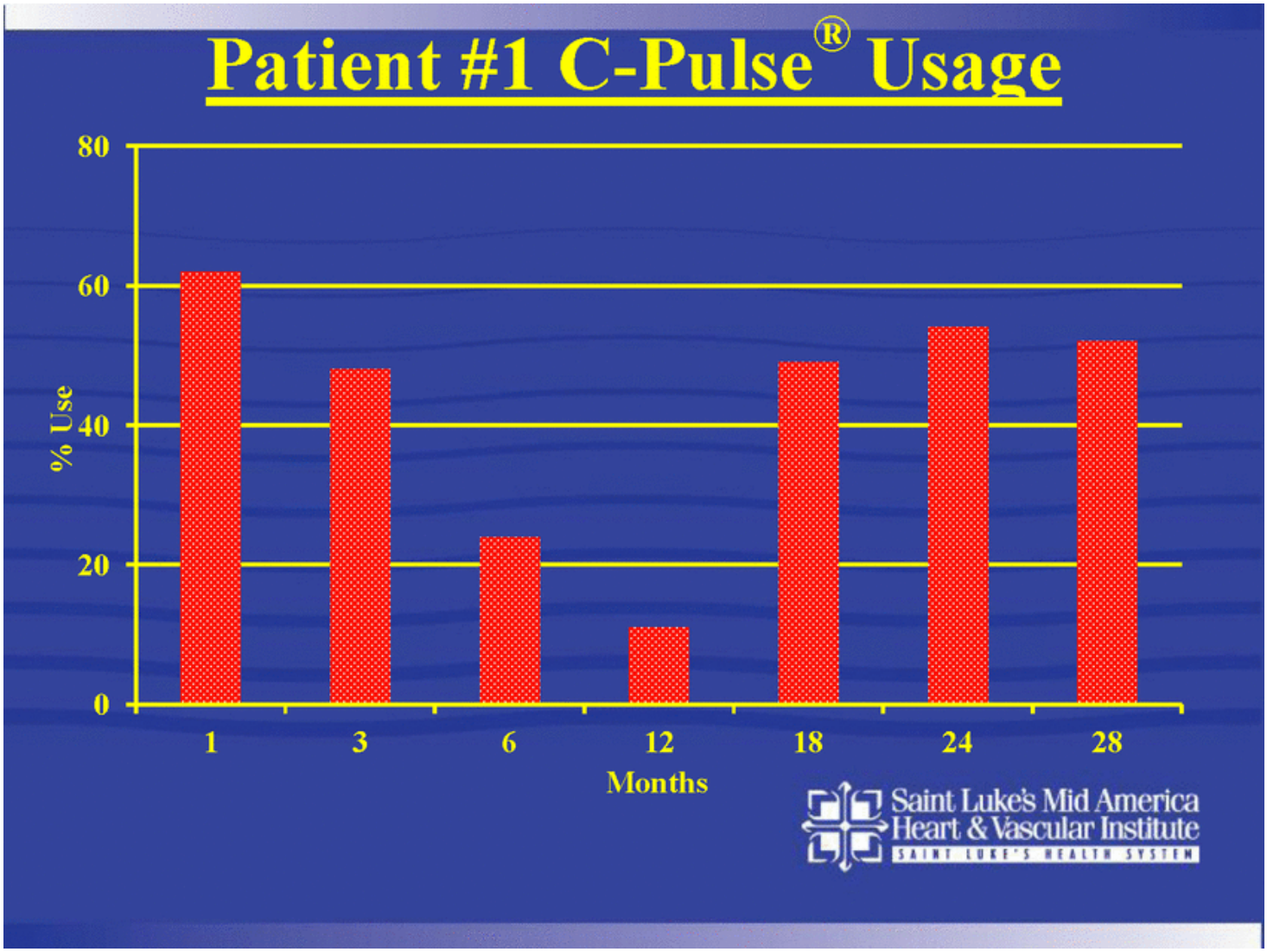
SAINT LUKE'S HEALTH SYSTEM

Patient #1 C-Pulse® Usage



Patient #1 - Lessons

- Patient clearly INTERMACS profile 4 at baseline
- Hemodynamics significantly improved by 6 months (60% improvement in cardiac index)
- No diuretic requirement since 5 months
- "Cialis" at 9 months
- 11% usage at 1 year
- Successful PIL explant 28 months

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SAINT LUKE'S HEALTH SYSTEM

Patient #2

- 36 yo with 10 year history of LBBB
- Finally diagnosed with HF 3 years prior
- Echo LVEF 21%
- Effort limitation at 3 blocks
- Too well for OHT
  - Peak VO2 19 ml/kg/min, 42% of predicted

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SAINT LUKE'S HEALTH SYSTEM

Patient #2

- Recently completed second master's degree
- Wanted to do anything possible to regain quality of life and return to work force
- NYHA class III
- Intermacs profile 7
- C-Pulse® placement 4/12
- Postop fevers ? Pericarditis
- Discharge POD 7
- Pre discharge echo EF 45%!

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Patient #2

- Excellent compliance 75-85%
- 7/13 – PIL issue necessitated C-Pulse® off for 48 hours – no symptoms
- 8/13 Stable on C-Pulse® 1:1 – given stability, decreased to 1:2
- 9/13 Stable on 1:2 – no symptoms - C-Pulse® turned off
- 10/13 Follow up echo pending – asymptomatic off C-Pulse®

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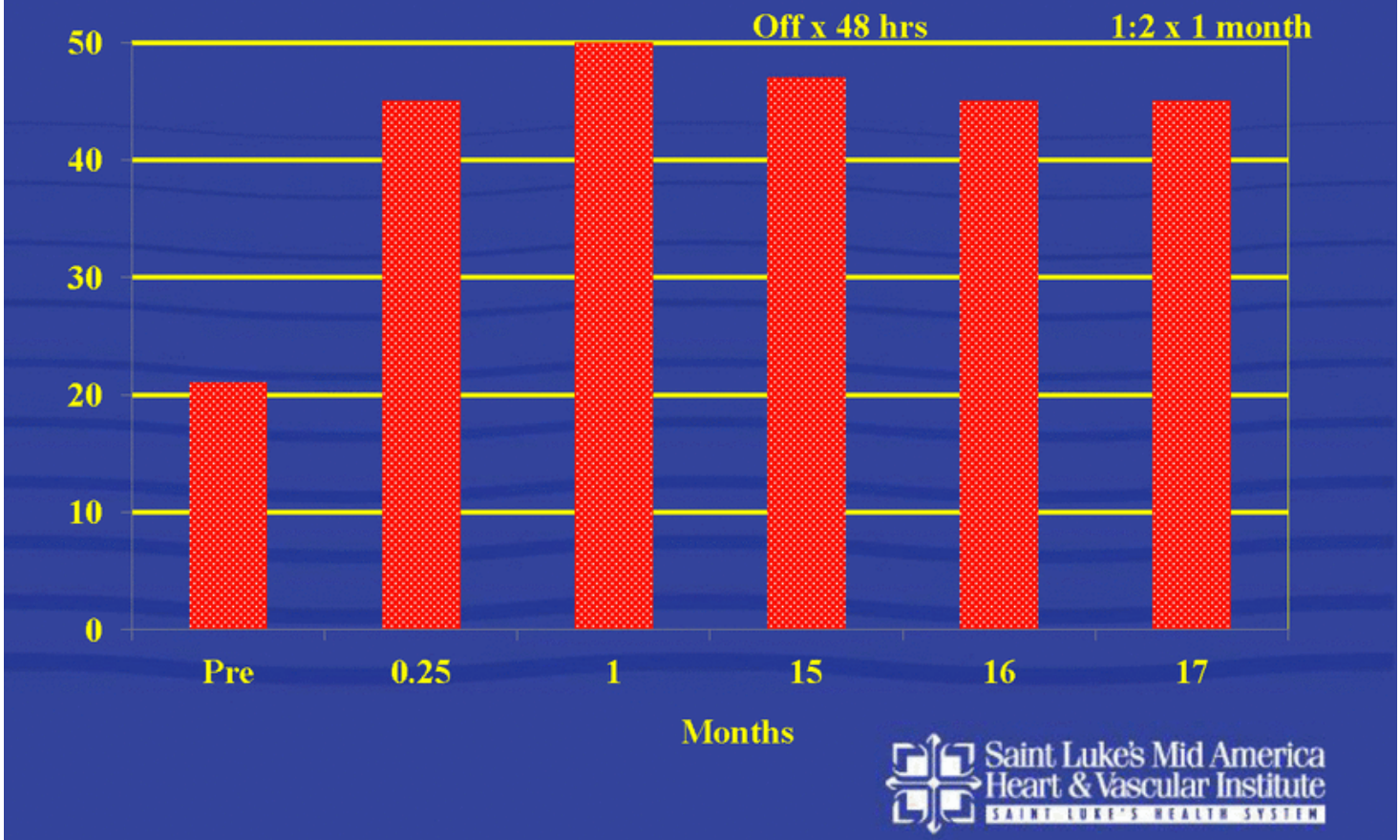
Patient #2 Serial LVEFs



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Patient #2 - Lessons

- Patient clearly INTERMACS profile 7 at baseline – HF treated 3 yrs prior but probably present for 10 yrs
- Significant sustained improvement of LVEF by 7 days postop
- Gradual "wean" 1:1 to 1:2 without symptoms
- Serial echos during weaning process showed no change of LVEF

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SAINT LUKE'S HEALTH SYSTEM

Patient #3

- 61 yo man s/p anterior STEMI 7/01 – LAD drug-eluting stent
- Post MI LVEF 30%
- LVEF 20% 2007 – ICD placement
- 2/10 – LLL nodule – biopsy non small cell, negative metastatic workup
  - LLLobectomy
  - Incidental finding of bronchoalveolar cell CA LUL s/p resection
  - No adjuvant therapy

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Patient #3

- 5/10 worsening HF
  - 90 degree orthopnea
  - Worsened renal function with diuresis
  - Milrinone begun – immediate improvement
  - 2 weaning attempts failed within hours – recurrent 90 degree orthopnea, oliguria, elevated creatinine
  - Home inotropes begun with stability
- Patient is clearly INTERMACS profile 3

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Patient #3

- Insurance would not pay for LVAD
- Right heart cath on milrinone – RA 8, PA 39/21/26, PCWP, CO/CI 4.3/2.2
- 8/10 C-Pulse® placement after 3 months of inotropic dependence
- Milrinone weaned off 2-3 hours postop after extubation
- 6 month RHC – RA 7, PA 47/25/31, PCWP 10, CO/CI 4.2/2.2

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SAINT LUKE'S HEALTH SYSTEM

Patient #3

- Currently NYHA II
- Has not required inotropes
- Several admissions for COPD only
  - Long smoking history
  - Lung resection
- Patient felt well enough to "self-wean" soon after 30 day time point

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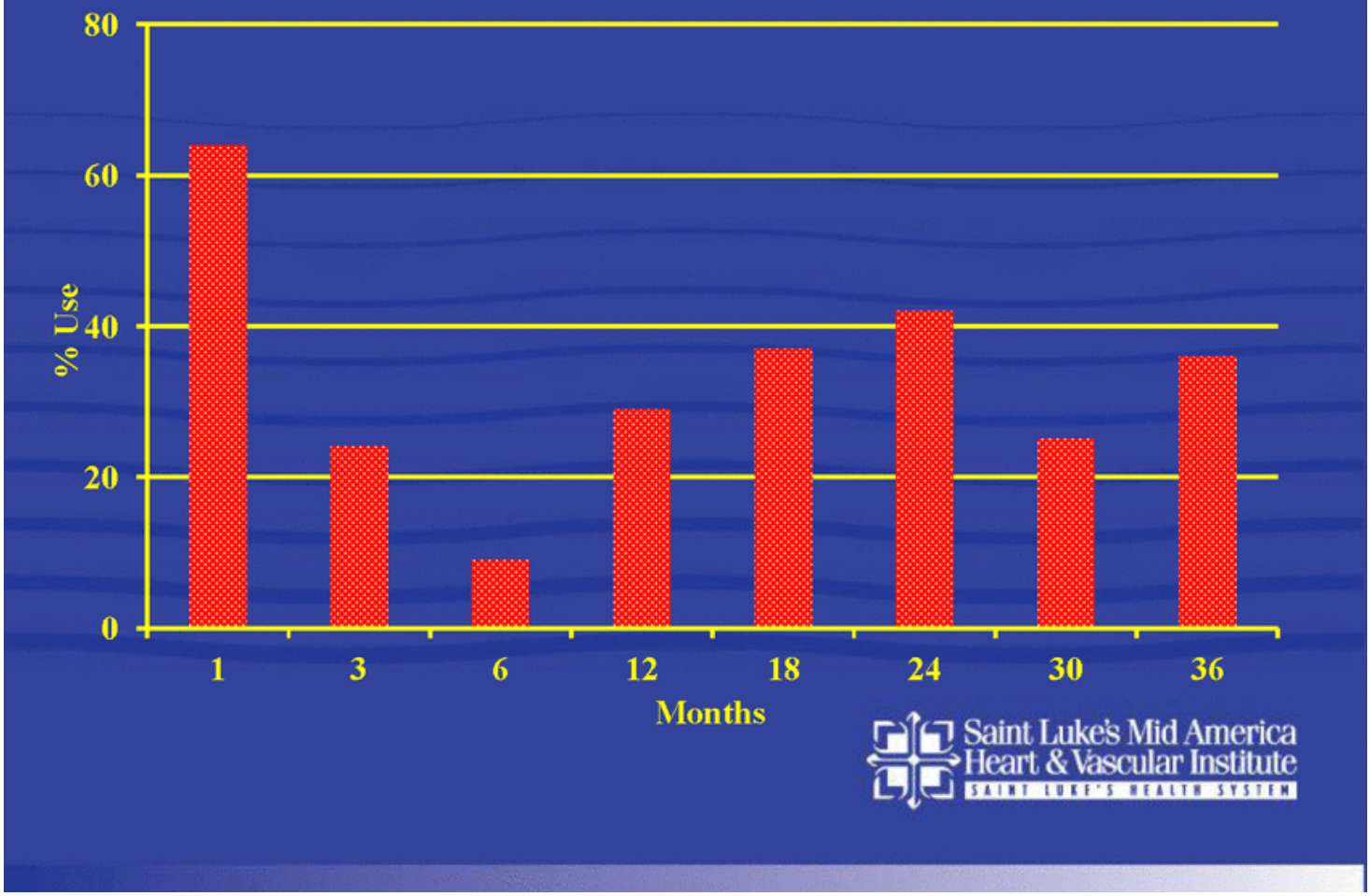
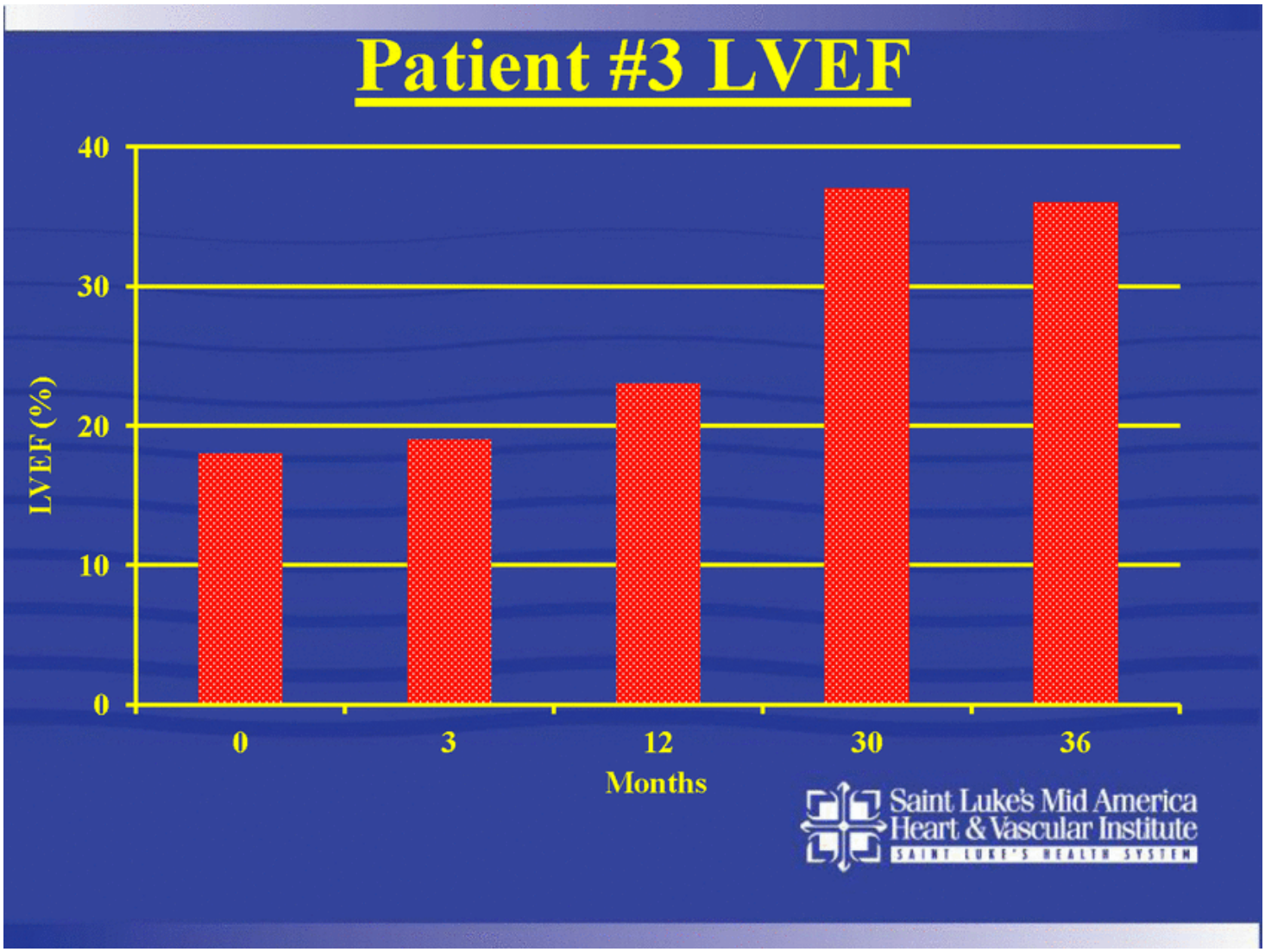
SAINT LUKE'S HEALTH SYSTEM

Patient #3 C-Pulse® Usage



Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM


Patient #3 LVEF
40
30
20
10
0
LVEF (%)
0
3
12
30
36
Months
Saint Luke's Mid America
Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

Patient #3 - Lessons

- Patient was clearly INTERMACS level 3
- C-Pulse® placement had same sustained hemodynamic effect as milrinone in this case
- Decrease in C-Pulse® usage suggests improvement in cardiac function
- C-Pulse® placement has helped him maintain HF stability for 3+ years

Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

Conclusion

- C-Pulse® implantation feasible via minimally invasive right thoracotomy
- Weaning of C-Pulse® support feasible after varying duration of hemodynamic support, with the potential for PIL explantation
- Further investigation will be necessary to confirm these single center observations

Saint Luke's Mid America Heart & Vascular Institute
SAINT LUKE'S HEALTH SYSTEM

Patient Video

Progress of the Fully Implantable System

TCT – October 2013

www.sunshineheart.com

Forward Looking Statement

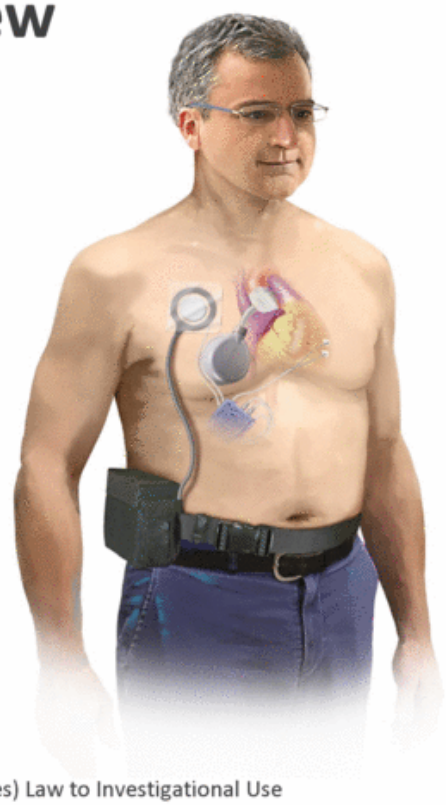
- This presentation contains forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties. Various factors could cause actual results to differ materially from these statements including timing, 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, 2012.
- 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 eliminates the percutaneous drive line and associated infection risks.

1.Non-blood contacting
2.Non-obligatory



CAUTION: Investigational device, limited by Federal (or United States) Law to Investigational Use

C-Pulse II Overview:

C-Pulse II - Fully Implantable System

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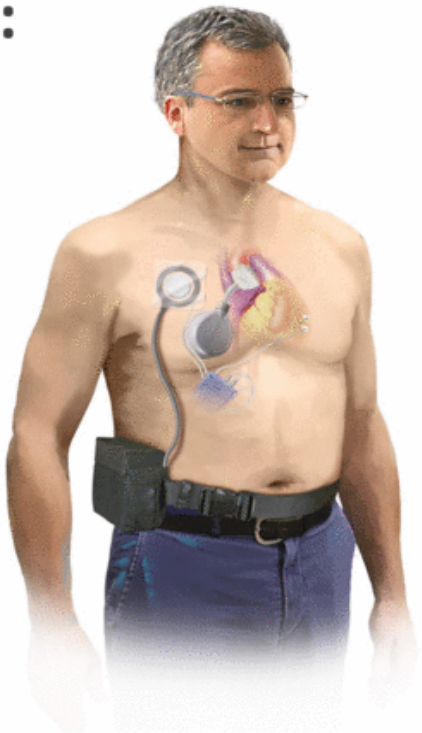
1.Non-blood contacting
2.Non-obligatory
3.No percutaneous drive line



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C-Pulse II Overview:

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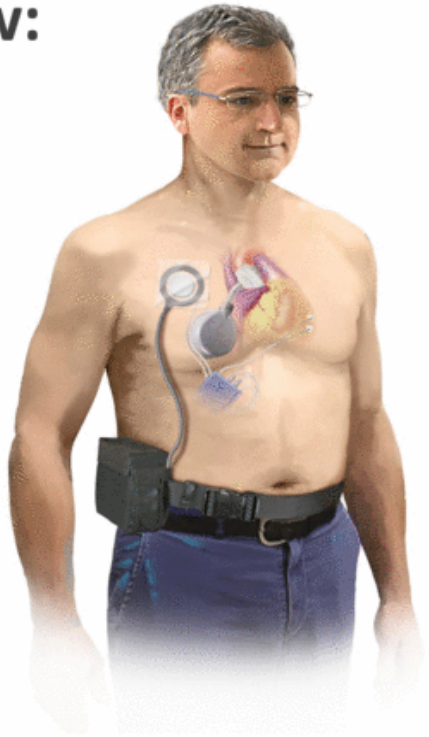
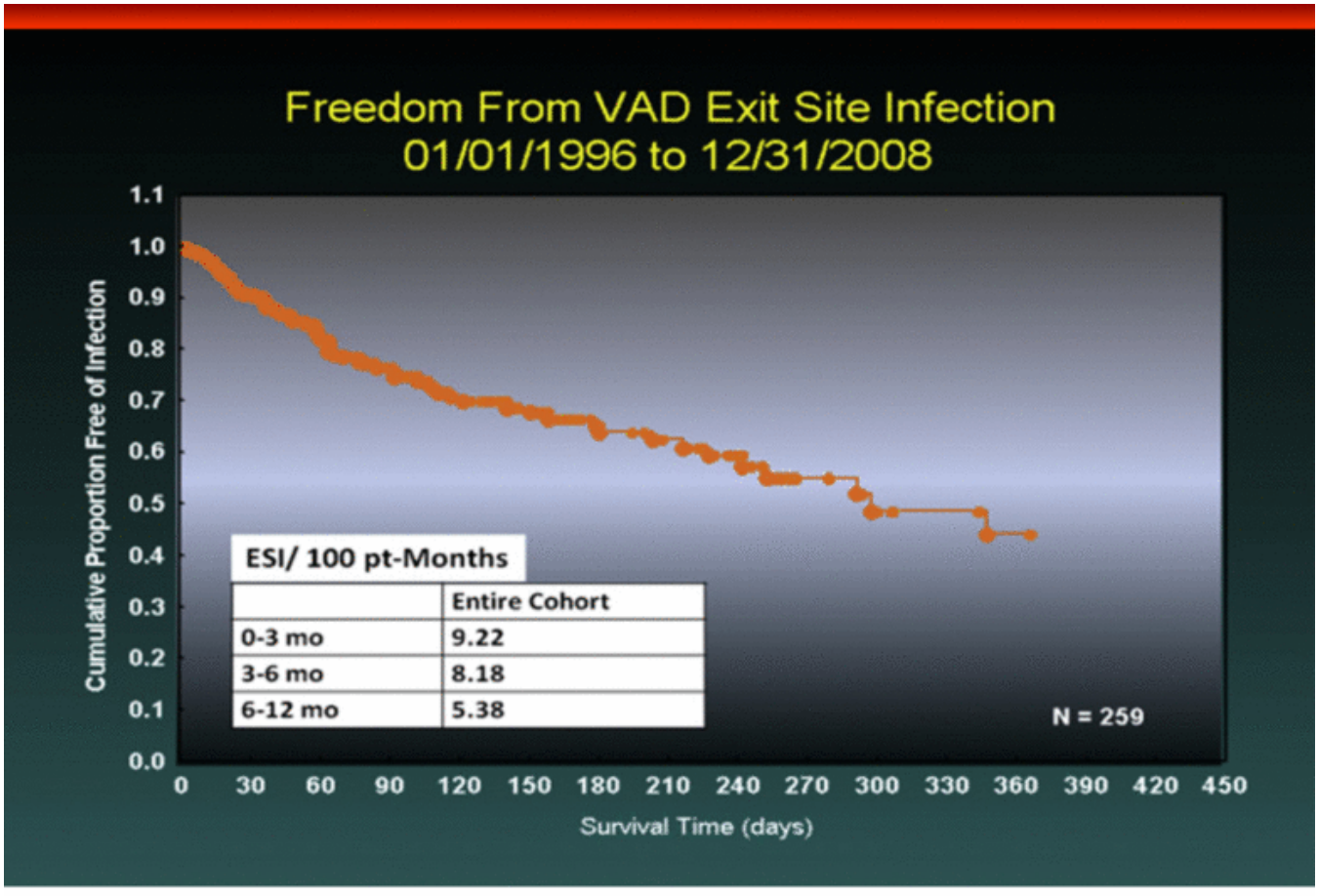
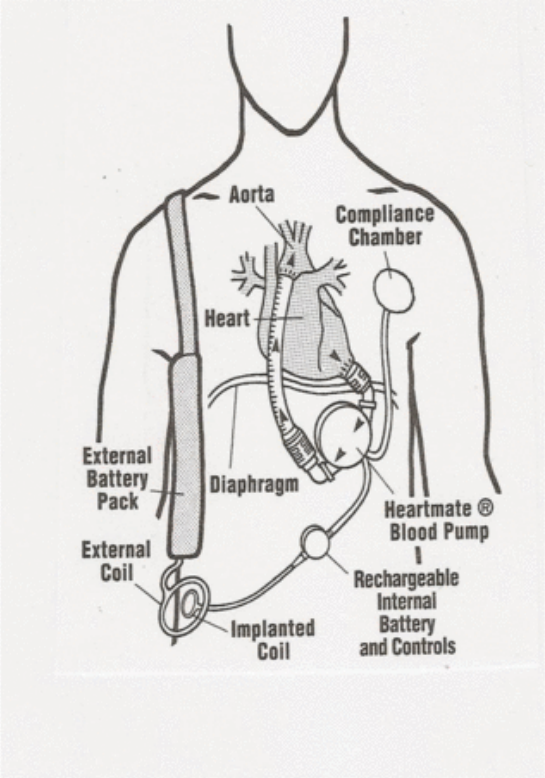


1.Non-blood contacting
2.Non-obligatory
3.No percutaneous drive line
4.No implanted battery

CAUTION: Investigational device, limited by Federal (or United States) Law to Investigational Use

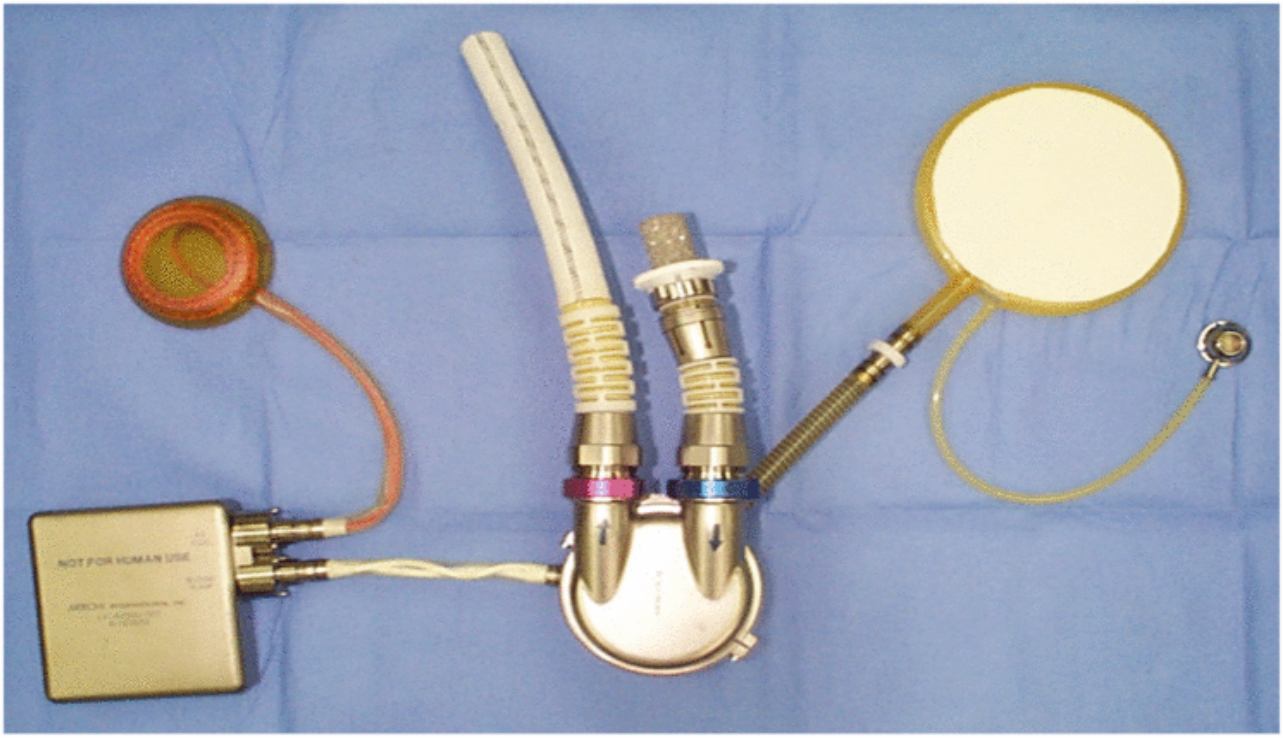


Eliminating the driveline is *not* a new idea…



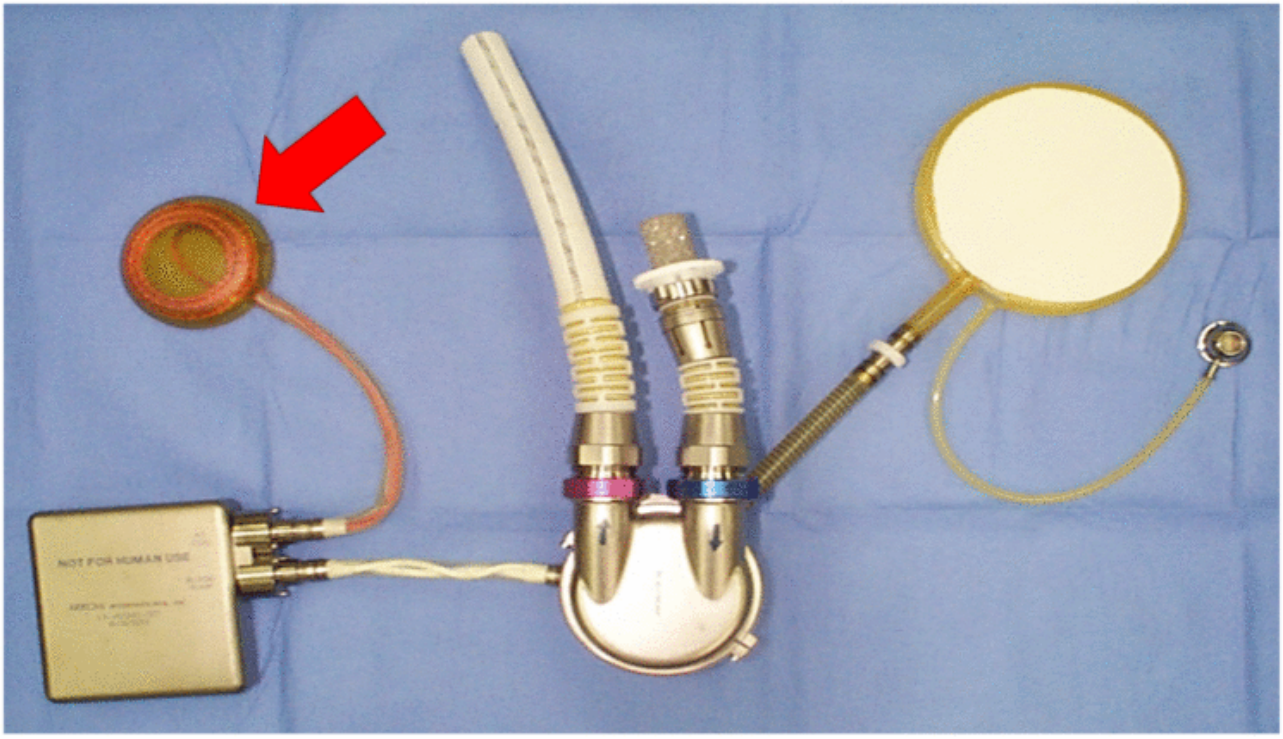
Circa 1985

Arrow LionHeart LVAD



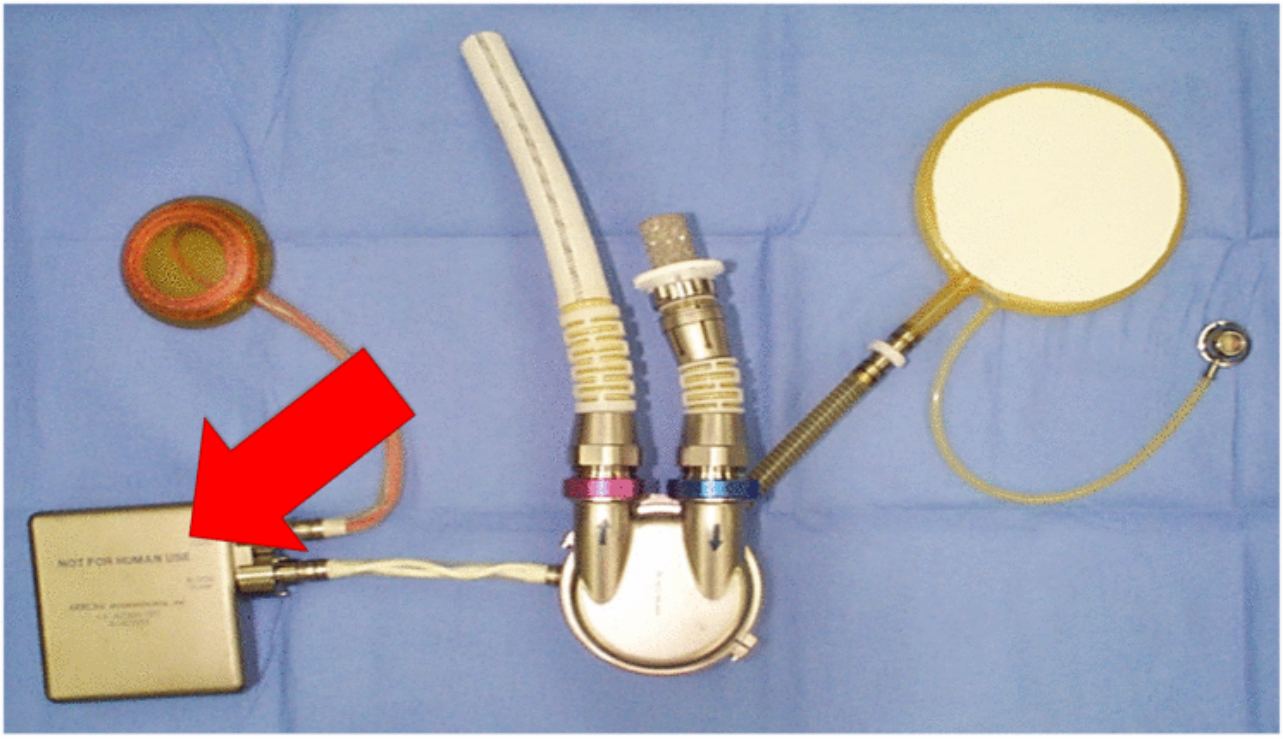
First clinical TETS system

Arrow LionHeart LVAD



First clinical TETS system

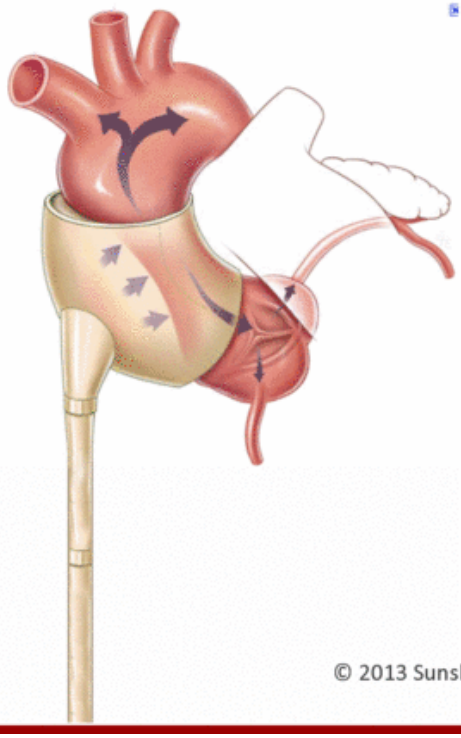
Arrow LionHeart LVAD

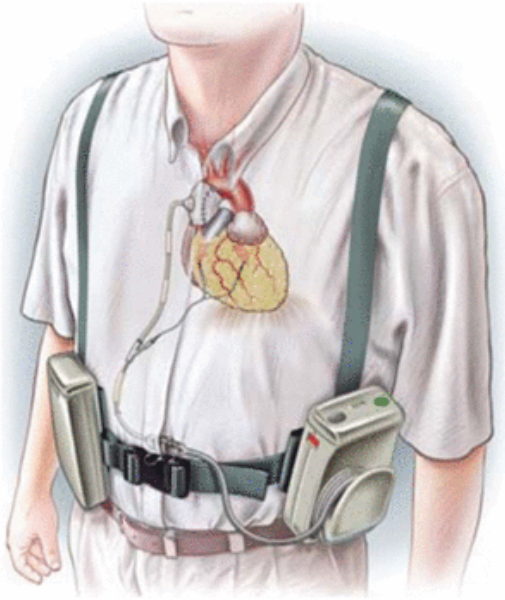


First clinical TETS system

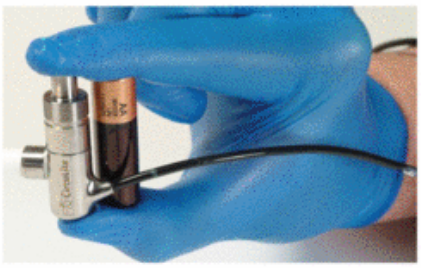
Where will clinical implementation of TETS technology first find traction?

SUNSHINE HEART C-pulse juxta-aortic balloon



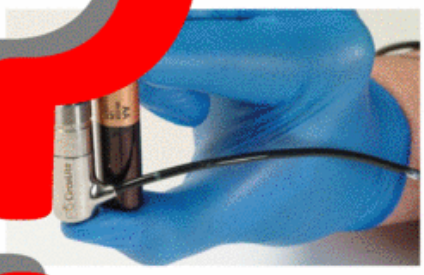



HEART
Assist 5



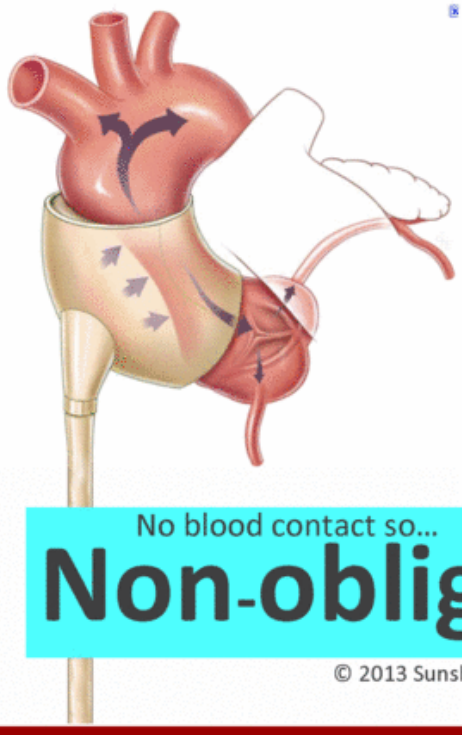

Berlin Heart


HEART
Assist 5




Berlin Heart

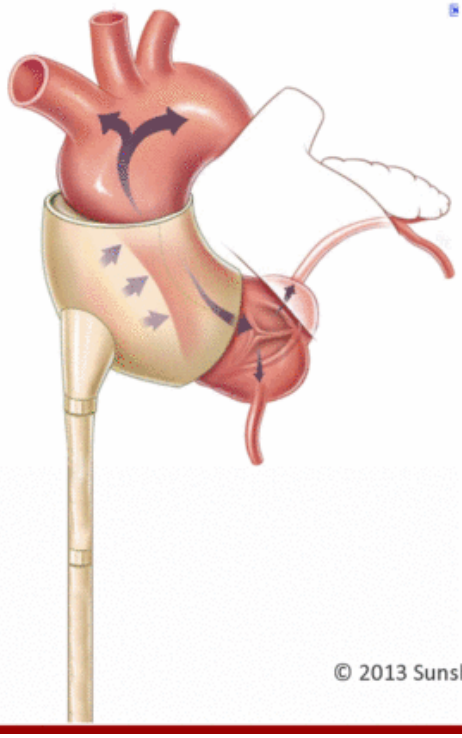
SUNSHINE HEART C-pulse juxta-aortic balloon

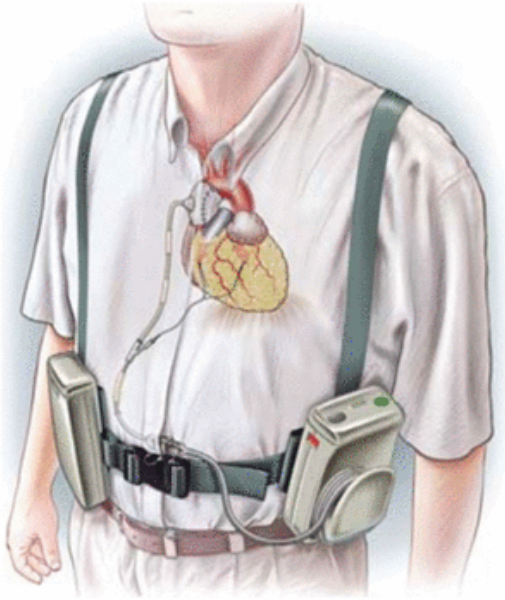


No blood contact so...

Non-obligatory

SUNSHINE HEART C-pulse juxta-aortic balloon





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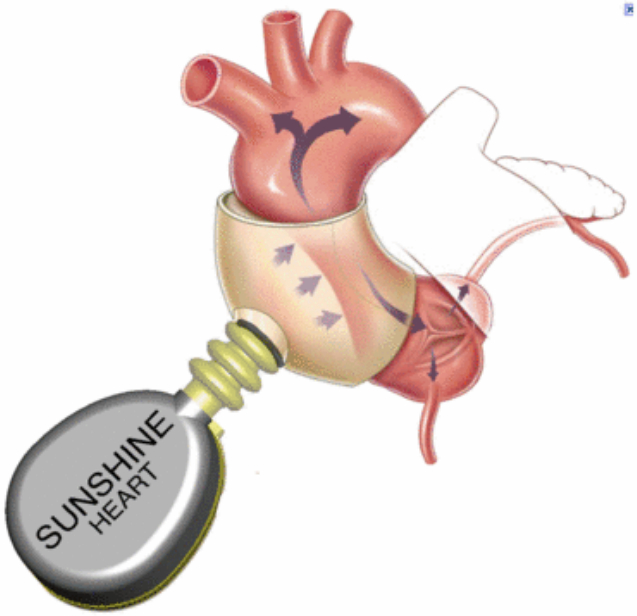
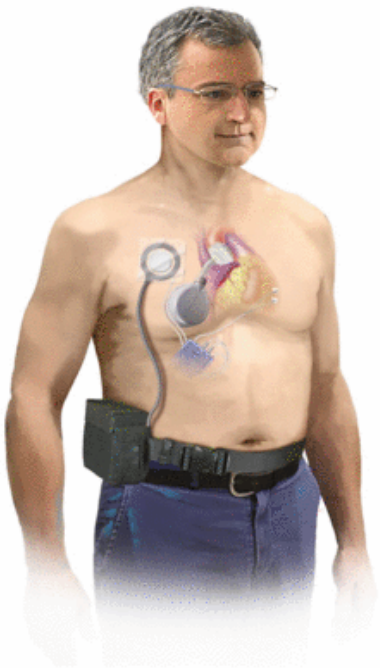
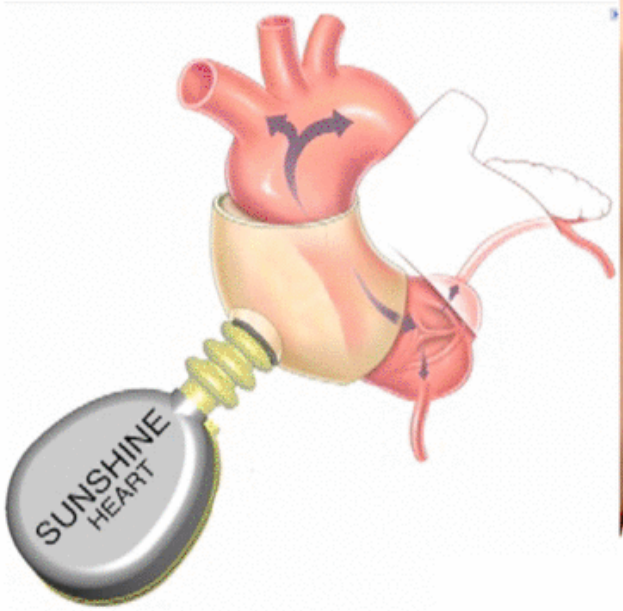
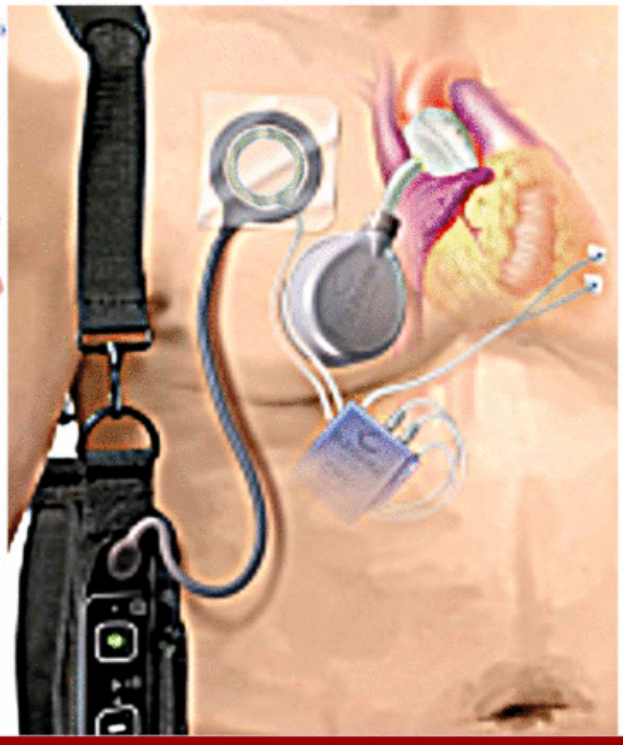
SUNSHINE HEART C-pulse II





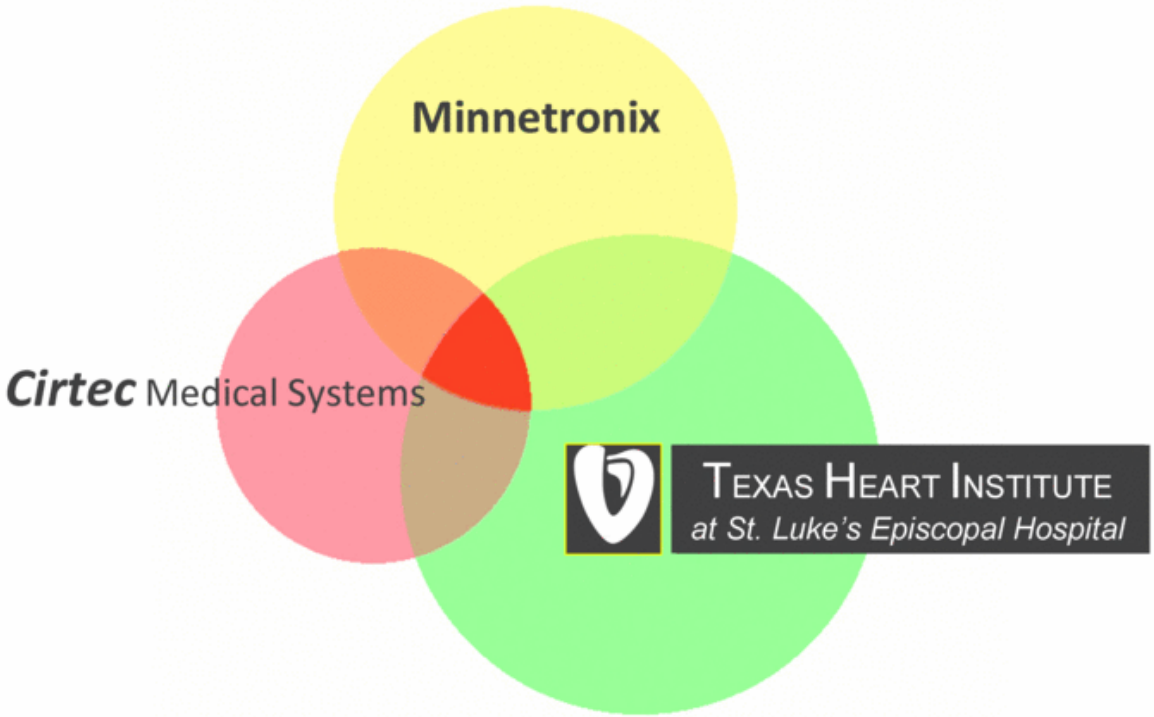
SUNSHINE HEART C-pulse II





Electrohydraulic pump…

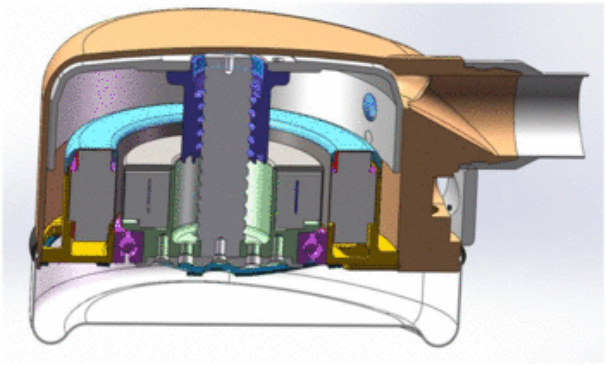
C-Pulse II – Leveraging powerful synergies

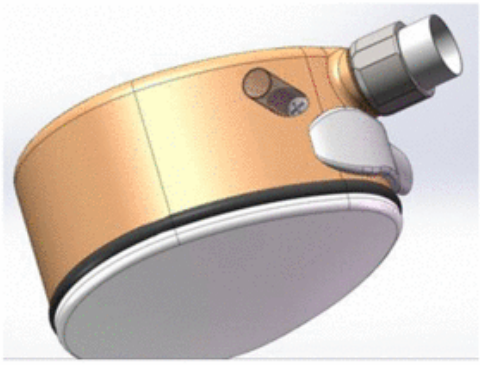


Electrohydraulic pump- *Cirtec* Medical Systems

SUNSHINE HEART

- Rapidly inflates and deflates the juxta-aortic balloon (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





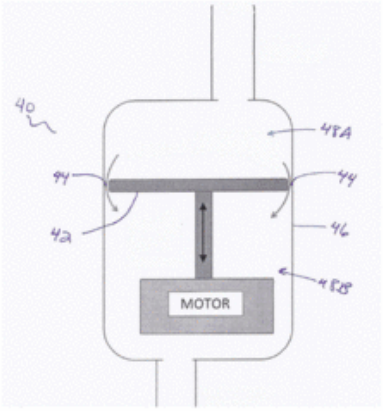
C-Pulse II – Important IP progress

SUNSHINE HEART

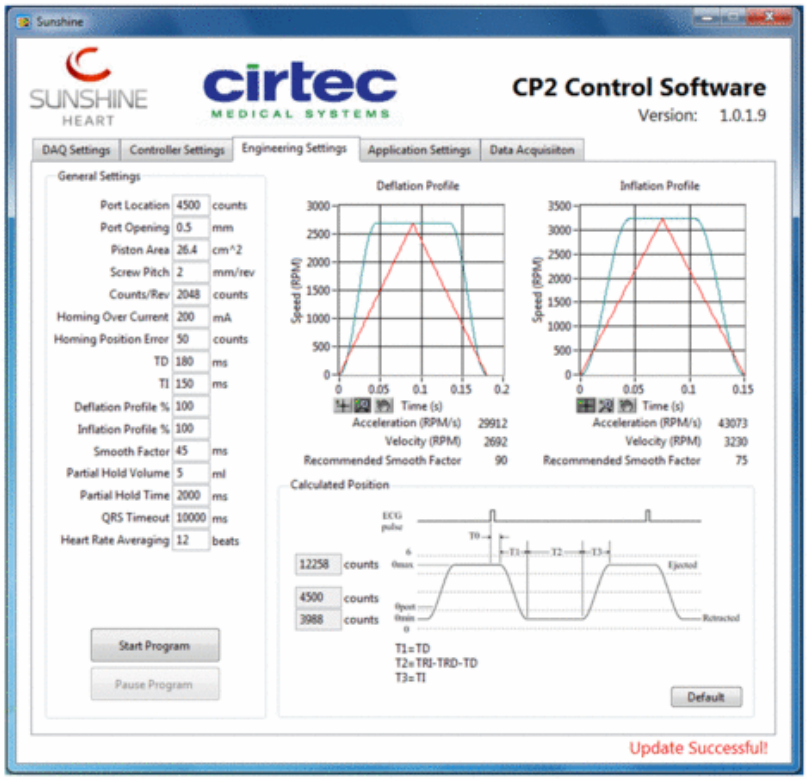
METHODS, SYSTEMS, AND DEVICES RELATING TO A FAIL-SAFE PUMP FOR A HEART ASSIST DEVICE

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.



Electrohydraulic pump- *Cirtec* Medical Systems

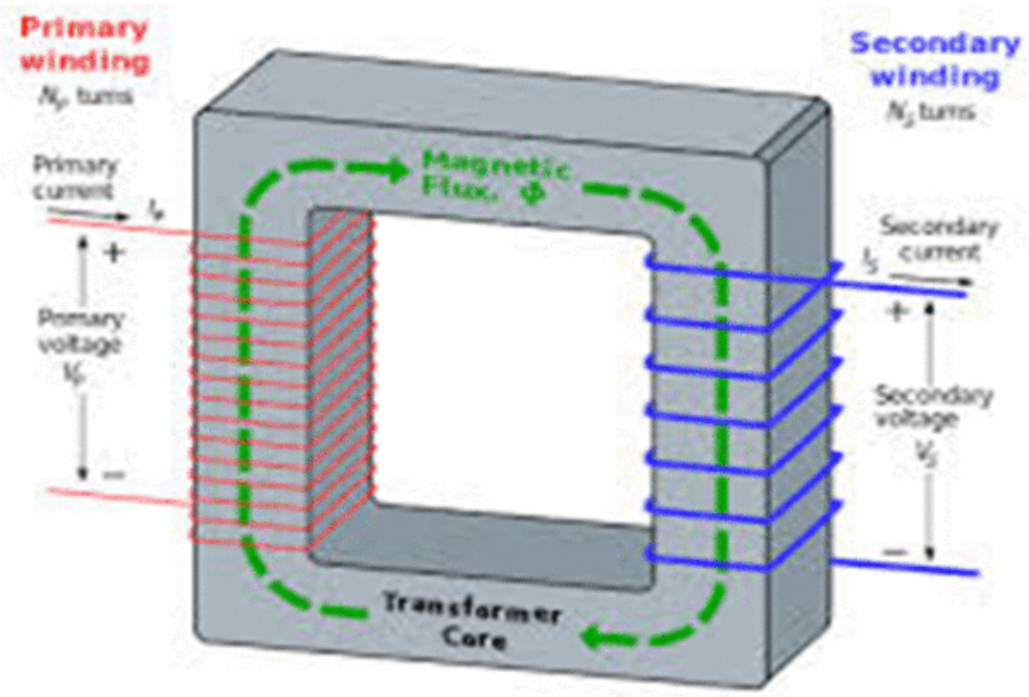


Trans-cutaneous Energy Transfer System (TETS)

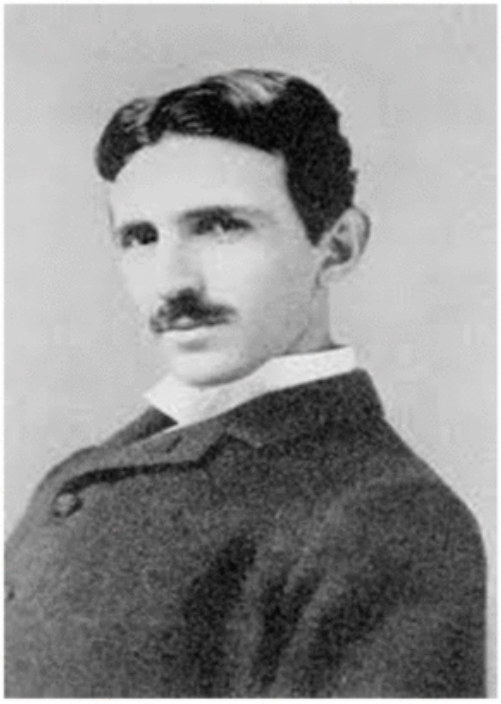
- DC battery pack outside the body
- DC current is put through an oscillator to make AC
- AC current is put through a large electro-magnetic coil (1º) to generate an oscillating magnetic field
- Oscillating magnetic field goes through the skin
- Oscillating magnetic field is picked up by a tuned internal coil (2º) resulting in induction of AC current
- AC current rectified into DC used to charge internal battery and run the LVAD

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

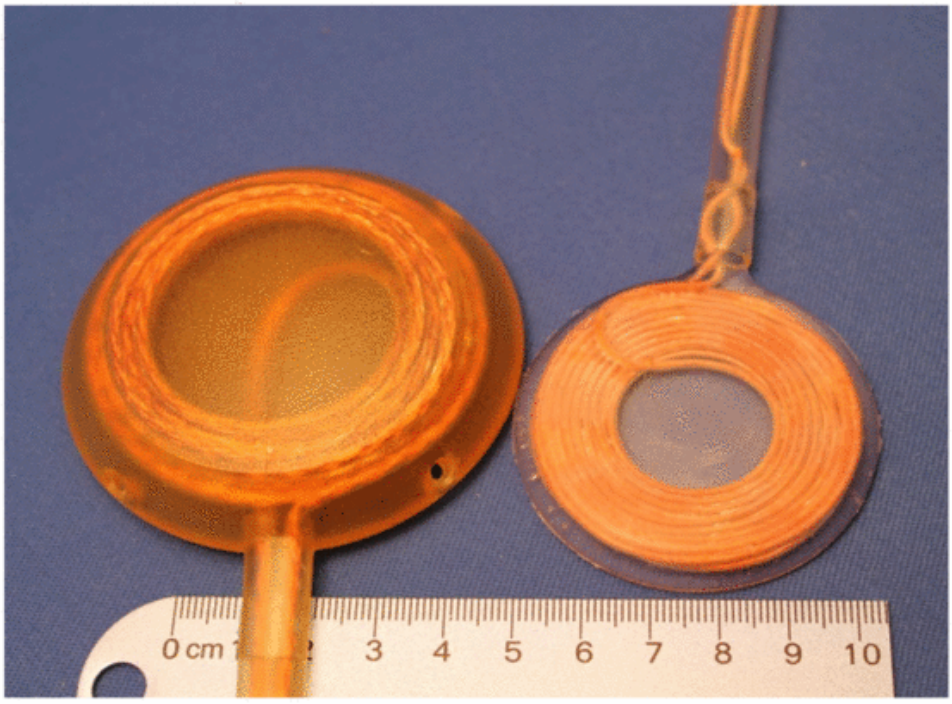
Minnetronix

Leaders in Transcutaneous Energy Transfer Systems (TETS)

Minnetronix

SUNSHINE HEART

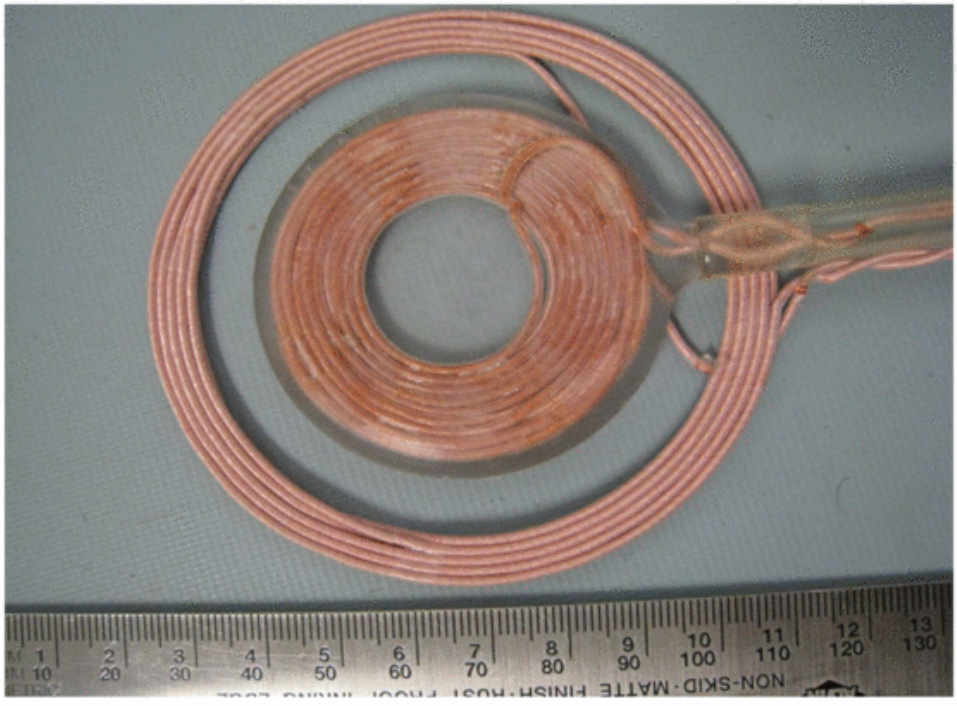
Improvement in TETS component geometry and function



Minnetronix

SUNSHINE HEART

Improvement in TETS component geometry and function




SUNSHINE
HEART
SUNSHINE
HEART
Where are we going to test it?


TEXAS HEART INSTITUTE
at St. Luke's Episcopal
Hospital

THI Cardio Vascular Research Lab ICU

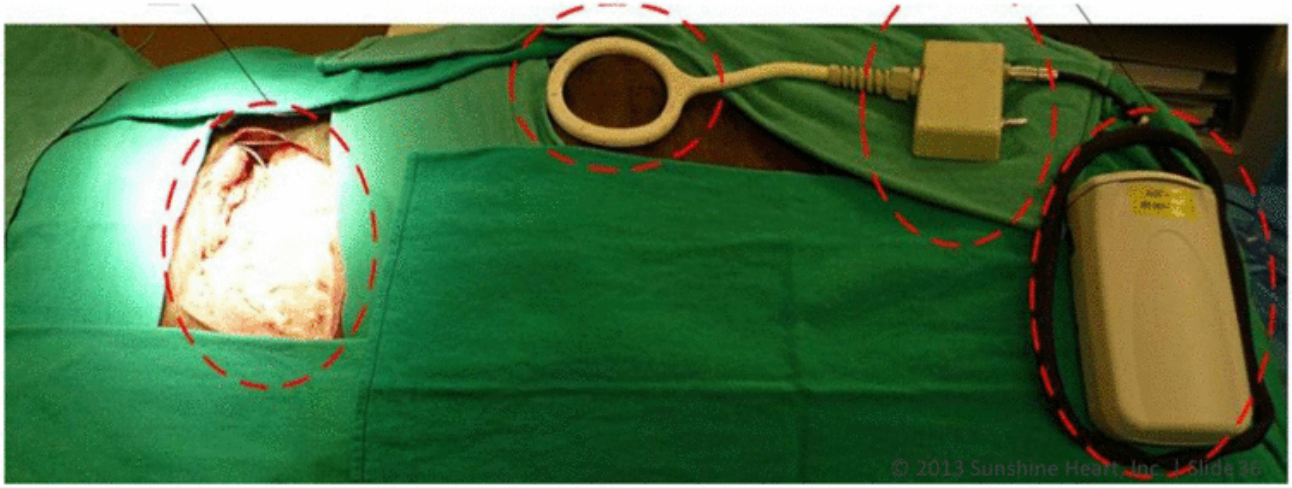
SUNSHINE HEART

THI Cardio Vascular Research Lab ICU

SUNSHINE HEART

Surgical Implant and System Integration

- THI's Cardio Vascular Research Lab
- 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)

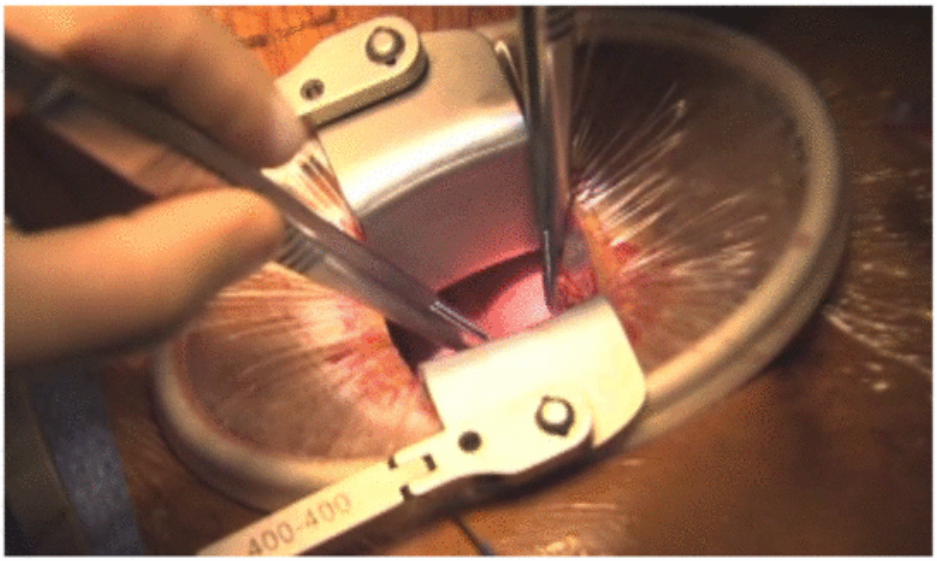


Minimally Invasive Implantation

Small incision

Sternal-sparing

No cardiopulmonary bypass



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