



UNIVERSITÀ DEGLI STUDI DI TORINO

ADVANCES IN CARDIAC ARRHYTHMIAS

and

GREAT INNOVATIONS IN CARDIOLOGY

XXVII GIORNATE CARDIOLOGICHE TORINESI

A NEW GENERATION OF

ARTIFICIAL HEARTS

Directors

Fiorenzo Gaitanari
Sebastiano Marra

Scientific Committee

Harold M. Beller, Usa
Martin Borggrefe, Germany
Amir Lerman, Usa

Prof Mauro Rinaldi

Turin

October 23-24, 2015

Centro Congressi
Unione Industriale di Torino



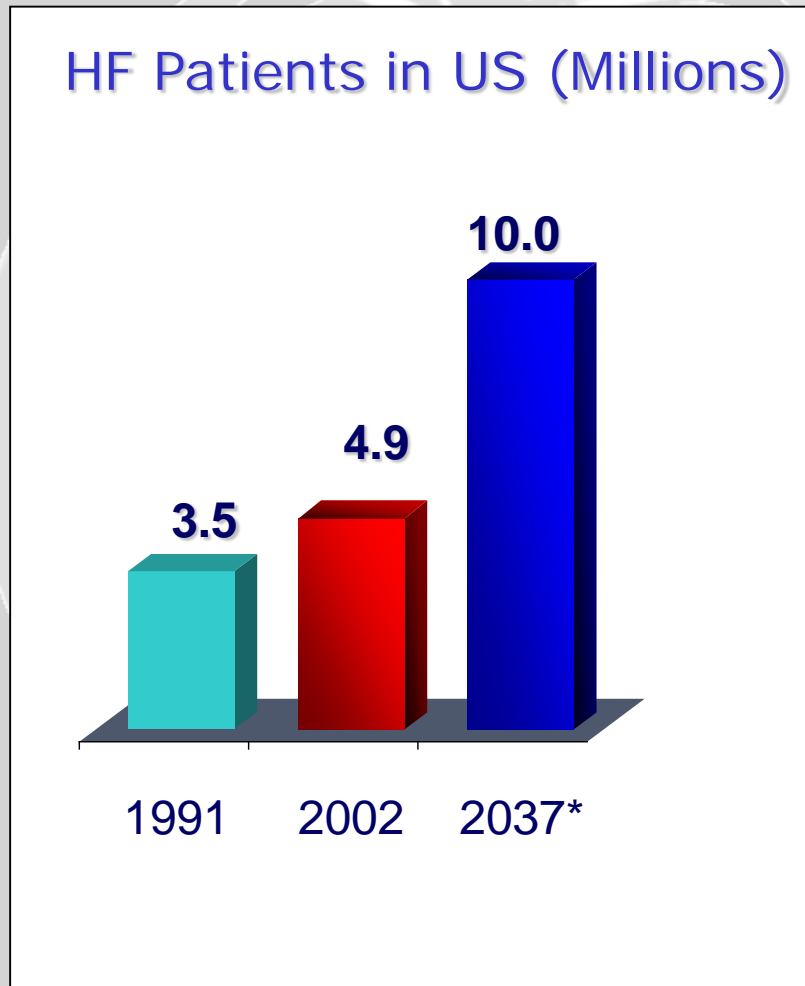
TURIN

MCS and HTX program since 2006...



251 heart transplantations
271 short term VAD implantations
74 permanent VAD implantations

Prevalence of Heart Failure in the United States



- 4.9 millions symptomatic patients; estimated 10 millions in 2037
- 550,000 new cases/year

*Rich M. *J Am Geriatric Soc.* 1997;45:968–974.

The New England Journal of Medicine

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NUMBER 20



LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE FOR END-STAGE HEART FAILURE

ERIC A. ROSE, M.D., ANNETINE C. GELIJNS, PH.D., ALAN J. MOSKOWITZ, M.D., DANIEL F. HEITJAN, PH.D.,
LYNNE W. STEVENSON, M.D., WALTER DEMBITSKY, M.D., JAMES W. LONG, M.D., PH.D., DEBORAH D. ASCHEIM, M.D.,
ANITA R. TIERNEY, M.P.H., RONALD G. LEVITAN, M.Sc., JOHN T. WATSON, PH.D., AND PAUL MEIER, PH.D.,
FOR THE RANDOMIZED EVALUATION OF MECHANICAL ASSISTANCE FOR THE TREATMENT OF CONGESTIVE HEART FAILURE
(REMATCH) STUDY GROUP*



2001

Kaplan-Meier estimates of survival at 1 and 2 years

Time point	LVAD (n=68)	Medical therapy (n=61)	p value
1 year	52%	25%	0.002
2 years	23%	8%	0.09

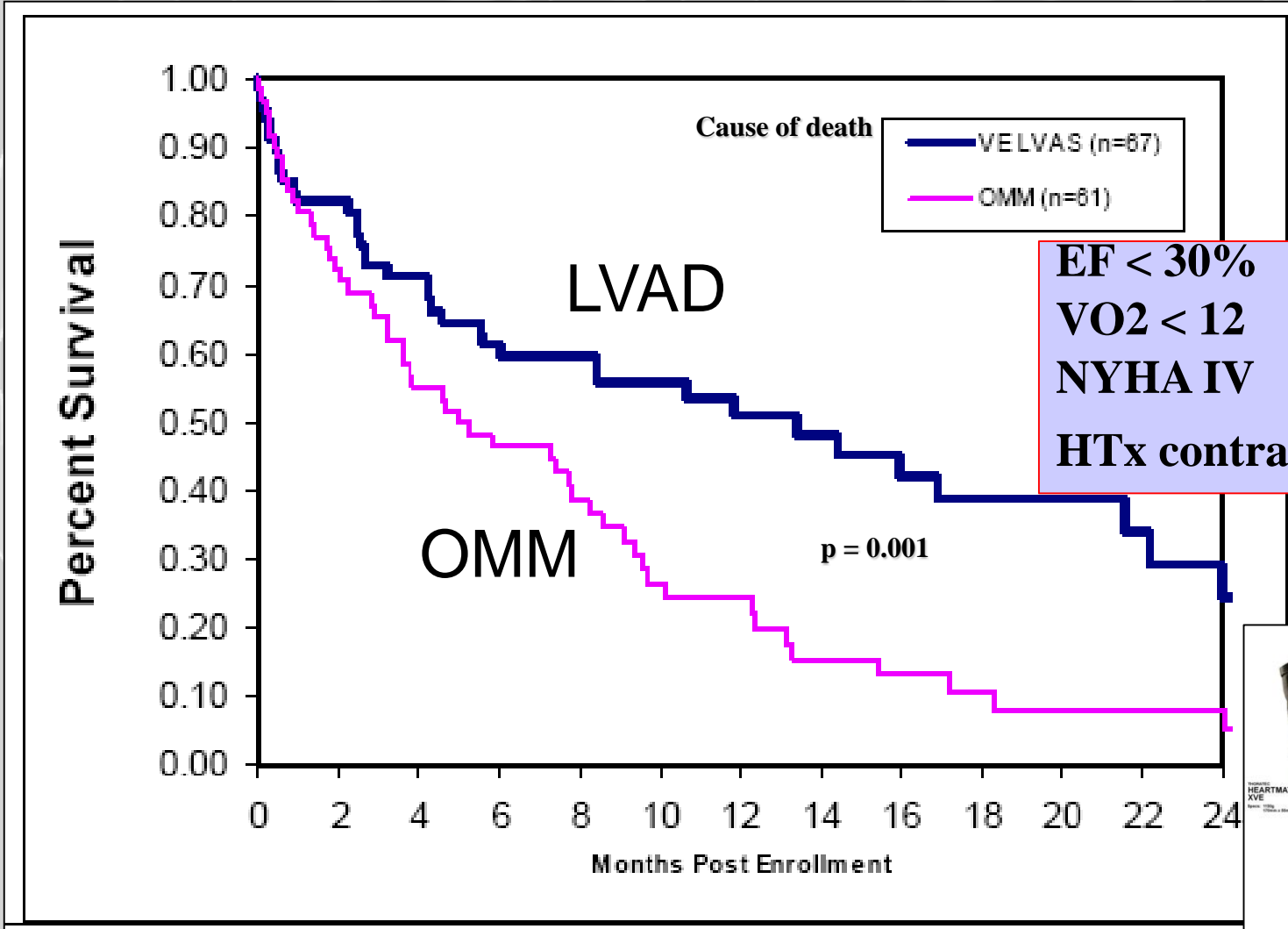
Rose EA et al. *N Engl J Med* 2001;345(20):1435-43.

NEJM 2001

First clinical trial

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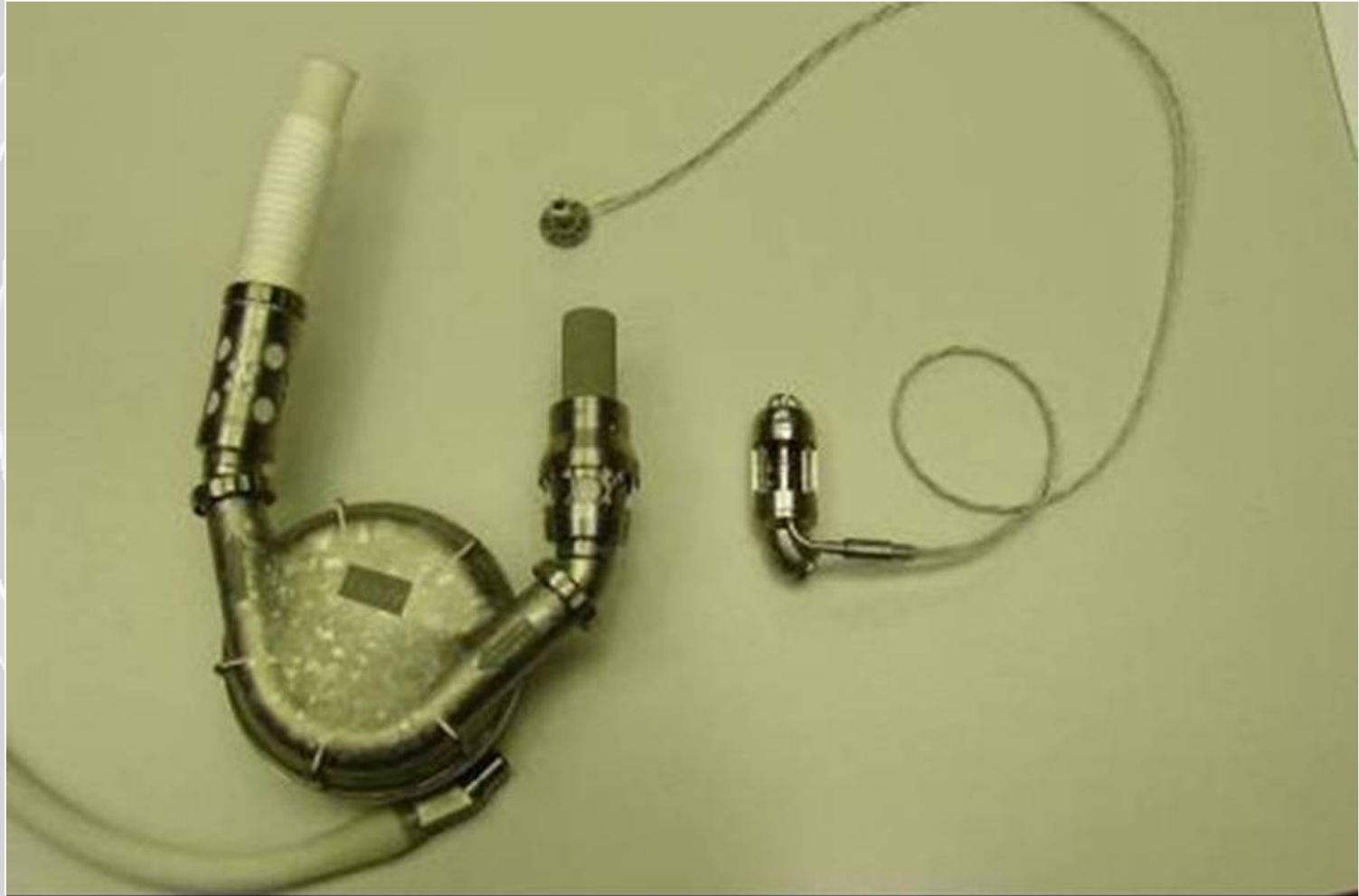


EF < 30%
VO2 < 12
NYHA IV
HTx contraindications



I GENERATION Devices

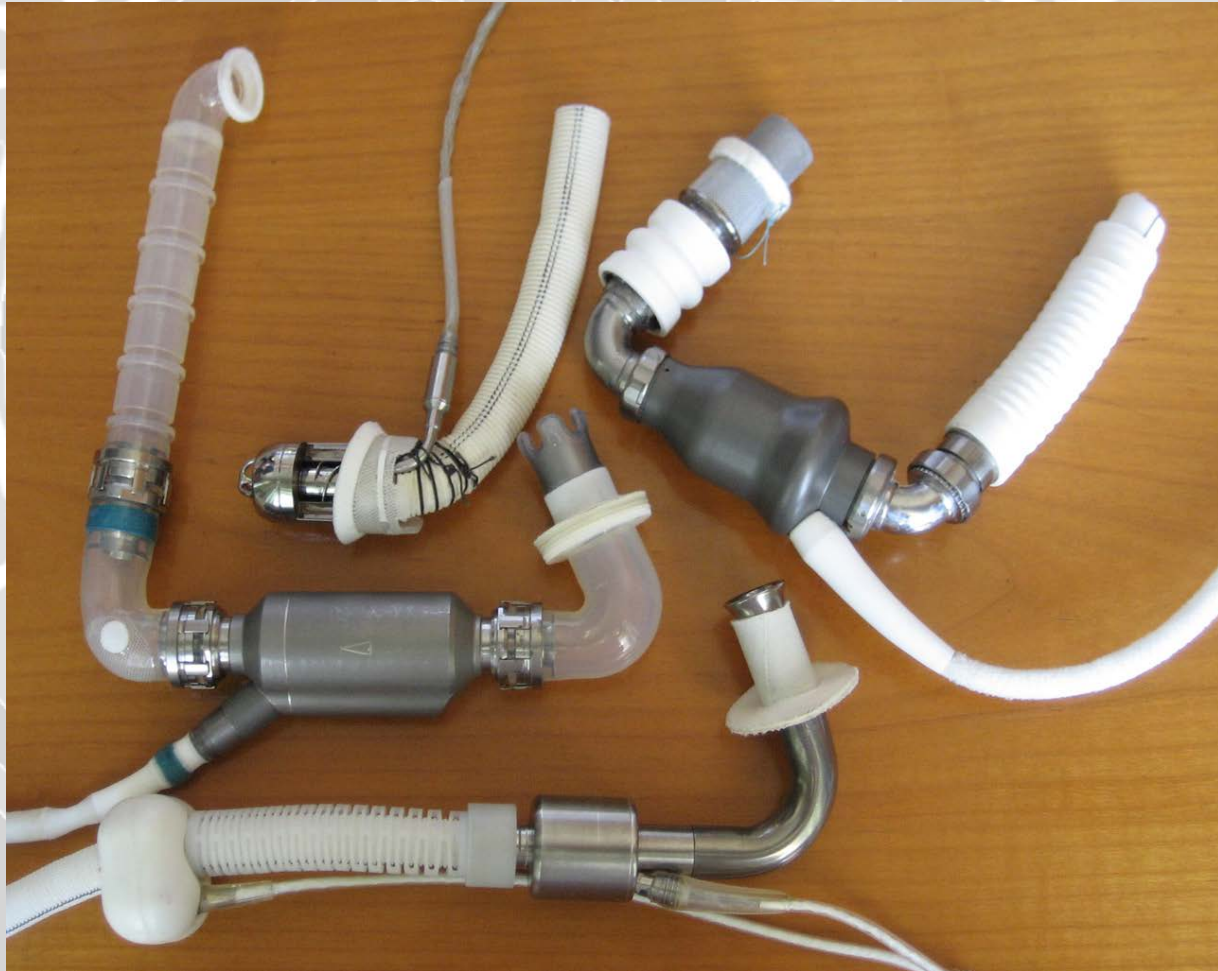
HeartMate I XVE



II GENERATION Devices

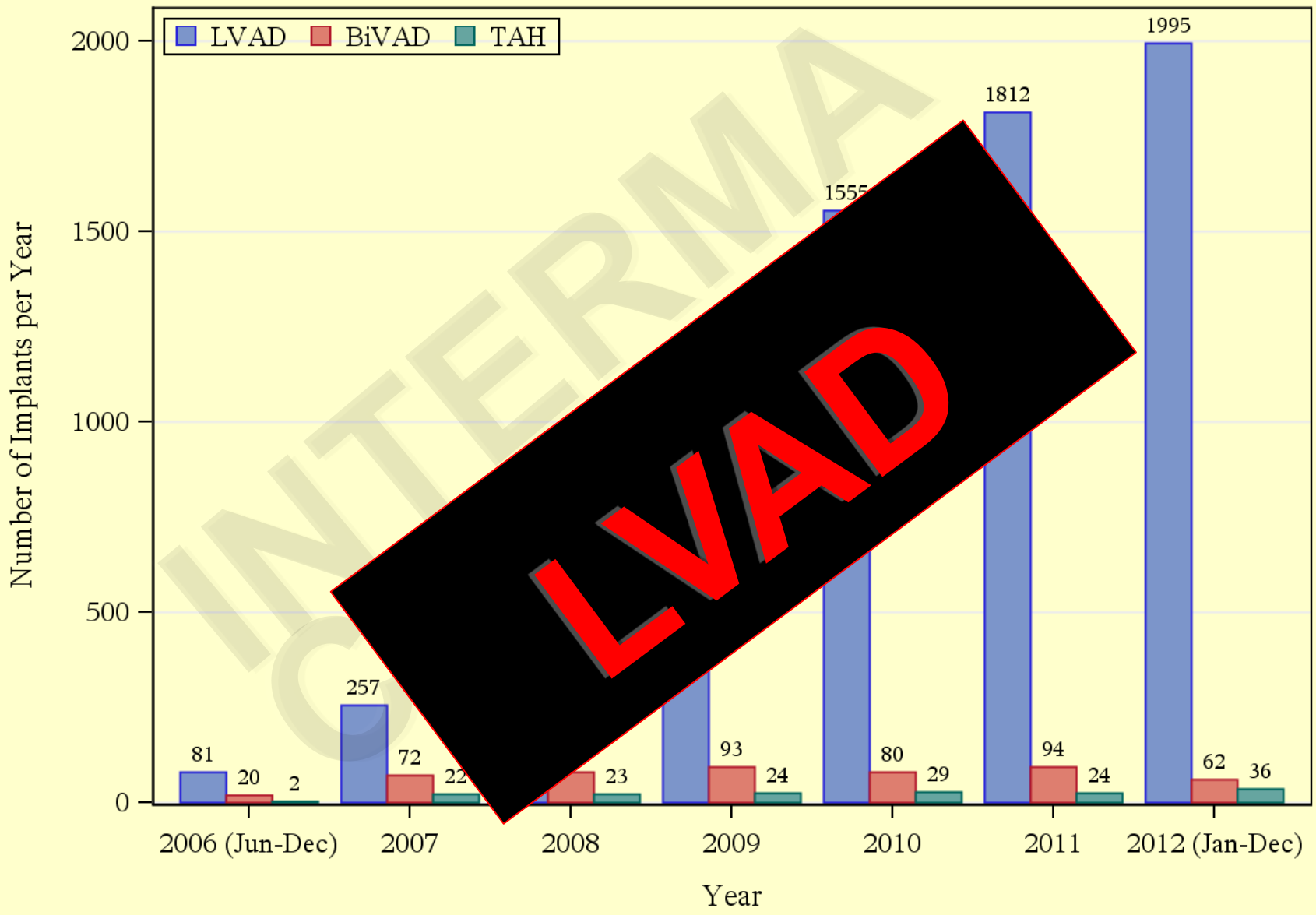
Since 2000...

*Clinical use of **Axial Continuous flow** devices*



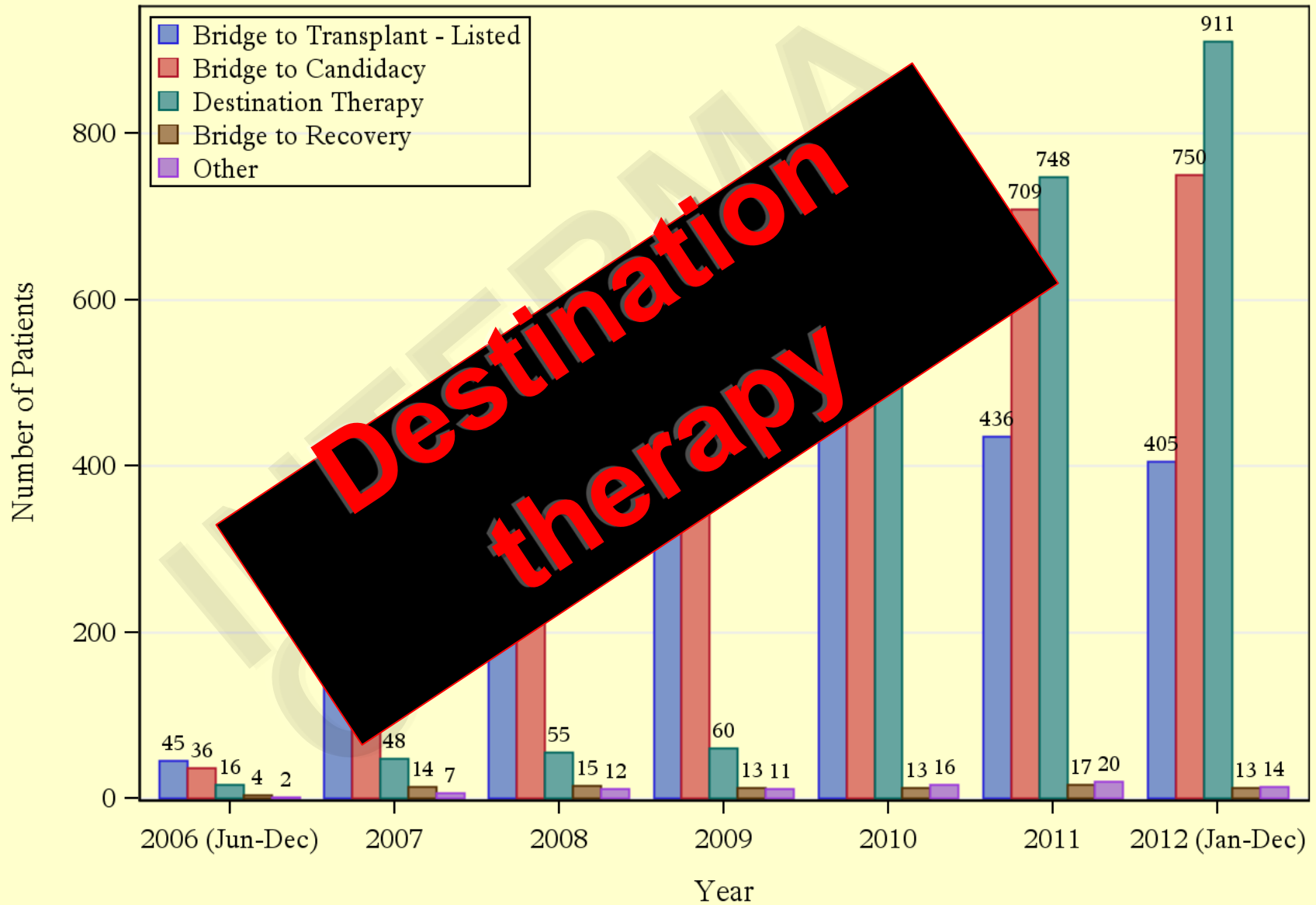
INTERMACS - Implants per Year by Device Type

Primary Prospective Implants: June 23, 2006 to December 31, 2012



INTERMACS - Implants per Year by Device Strategy

Primary Prospective Implants: June 23, 2006 to December 31, 2012



Sixth INTERMACS annual report: A 10,000-patient database

James K. Kirklin, MD,^a David Robert L. Kormos, MD,^c Lynn Marissa A. Miller, DVM, MPH, and James B. Young, MD^g

From the ^aDepartment of Surgery, University of Michigan, Ann Arbor, Michigan; ^cDepartment of Surgery, University Hospital, Pittsburgh, Pennsylvania; ^eDepartment of Surgery, Massachusetts General Hospital, Boston, Massachusetts; ^fDepartment of Pediatrics, Johns Hopkins University School of Medicine, Baltimore, Maryland; ^gDepartment of Surgery, Cleveland Clinic Foundation, Cleveland, Ohio.

J Heart Lung Transplant 2014;33:5

InterMACS Implants for Destination Therapy: June 2006 – December 2013, n = 3516

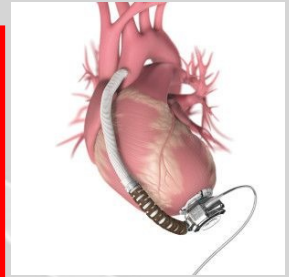
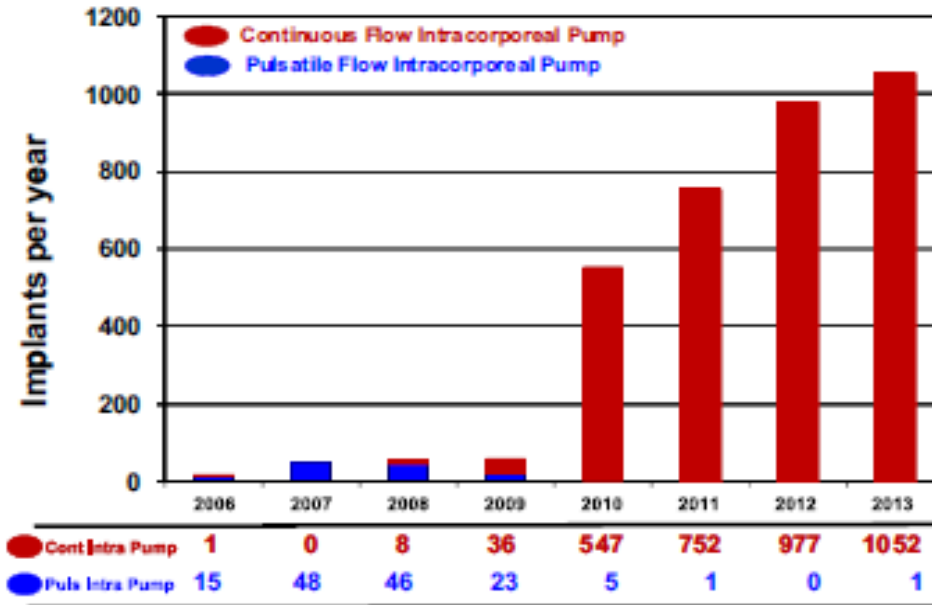


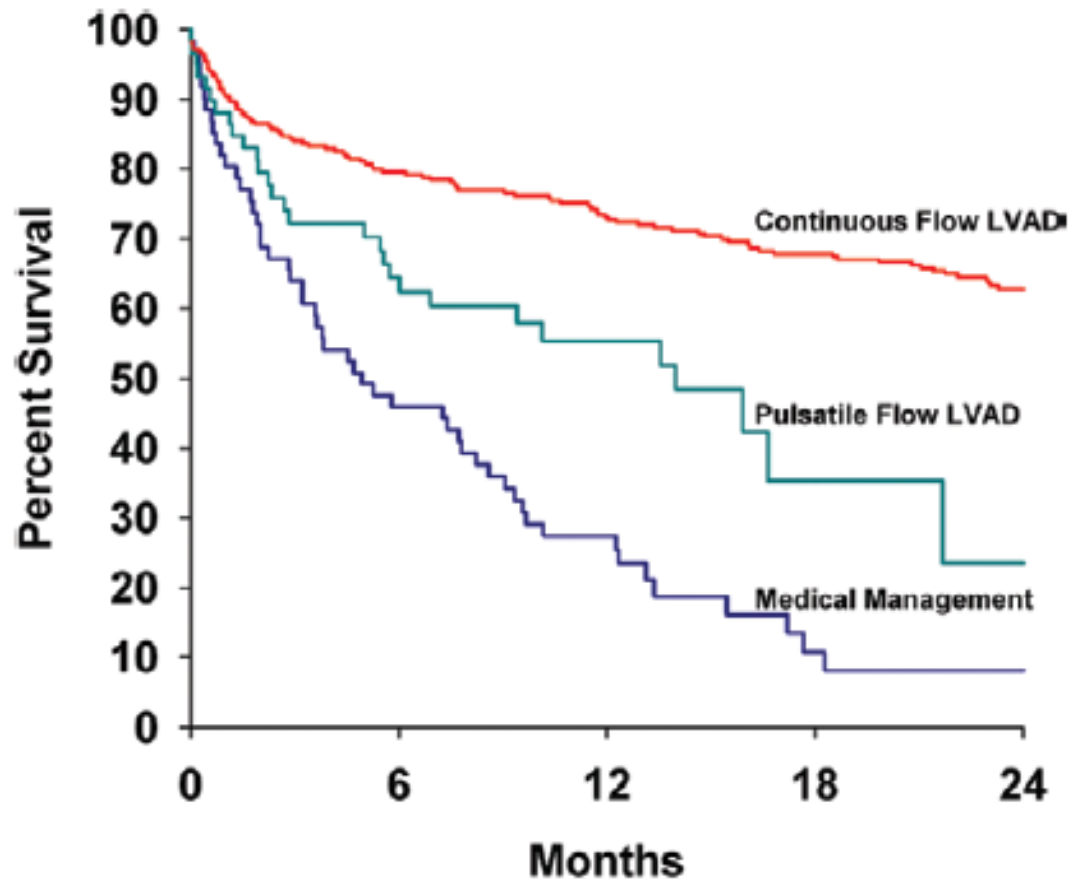
Table 4 Implants: June 2006 to December 2013 (N = 10,542)

Device strategy at time of implant	Implant date era							
	2006–2007		2008–2010		2011–2013		Total	
	n	%	n	%	n	%	n	%
BTT listed	185	42.4%	1,335	39.2%	1,453	21.7%	2,973	28.2%
BTT likely	85	19.5%	884	26.0%	1,474	22.0%	2,443	23.2%
BTT moderate	49	11.2%	337	9.9%	677	10.1%	1,063	10.1%
BTT unlikely	28	6.4%	104	3.1%	222	3.3%	354	3.4%
DT	64	14.7%	666	19.6%	2,786	41.6%	3,516	33.4%
BTR	17	3.9%	38	1.1%	38	1.0%	93	0.9%
Rescue therapy	8	1.8%	24	1.0%	28	0.4%	60	0.6%

Incremento dei pazienti in destination therapy negli ultimi anni

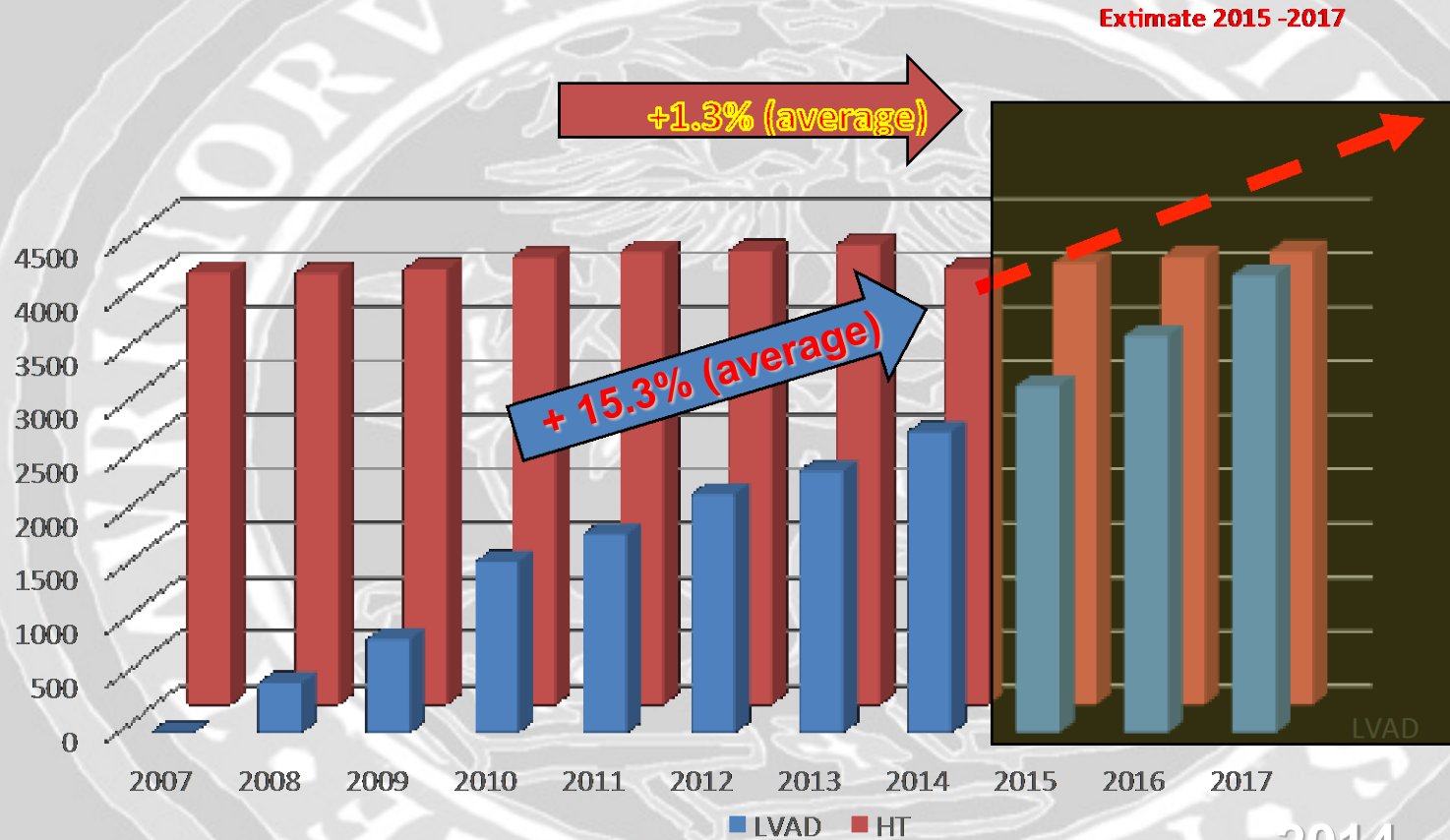
Cost of Ventricular Assist Devices: Can We Afford The Progress? Leslie W. Miller, Maya Guglin and Joseph Rogers

Circulation. 2013;127:743-748



2013

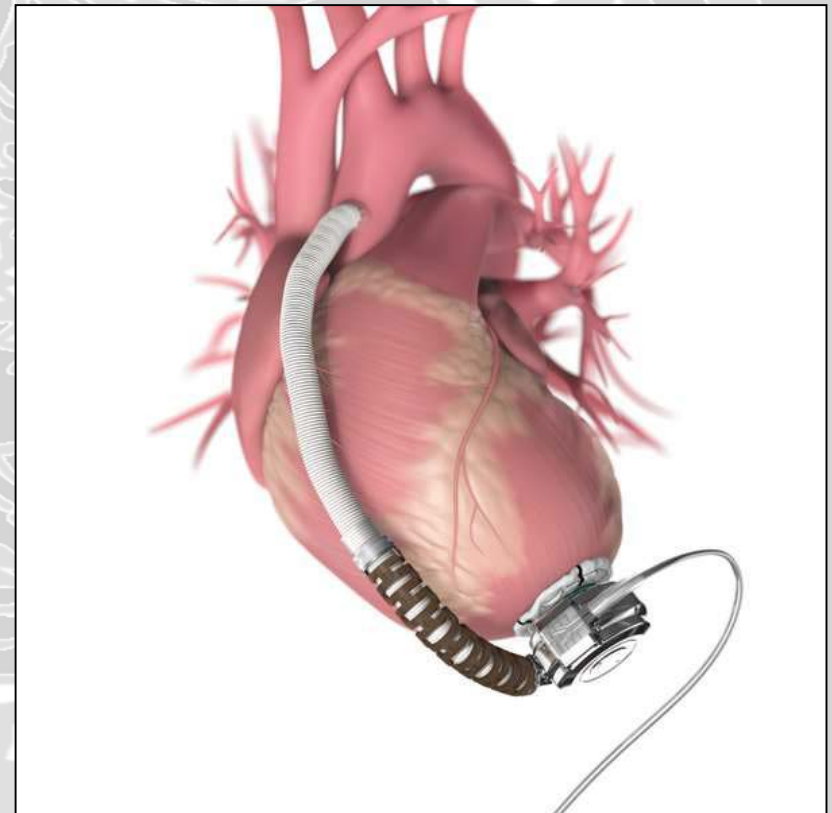
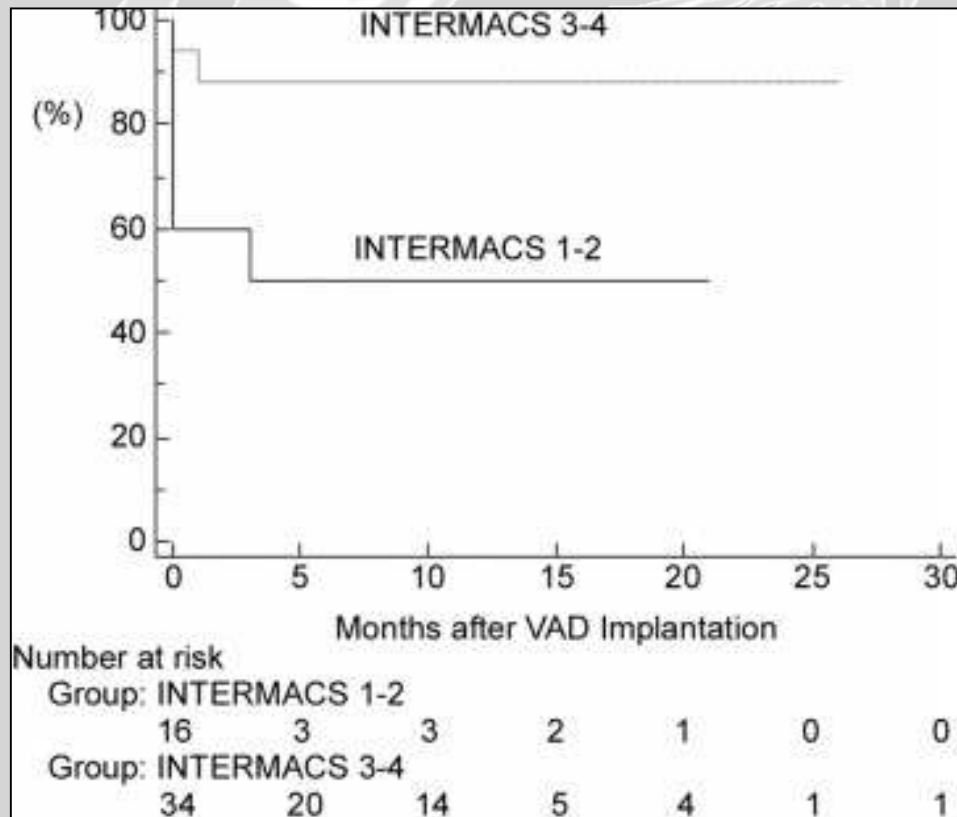
LVAD vs Heart Transplantation



III GENERATION Devices

Heartware- VAD

ADVANCED- CAP Trial 2013



Largest to smallest ...in ten years...

4° Generation

100 grams



92 grams



3° Generation



500 grams

2° Generation



300 grams



1° Generation

750 grams



100 grams

1000 grams

IV GENERATION Devices

HeartMate III

Ultra-Compact, Fully Magnetically Levitated VAD



Features

- Full support (10L / min) in ultra-compact size
- Artificial Pulse
- Small Pocket Controller
- Improved, modular driveline
- Intrathoracic placement

Expected Benefits

- Incorporates critical HeartMate® family design elements (e.g. large gaps, textured blood contacting surfaces)
- Potential for reduction of adverse events (AI, bleeding, thrombus, stroke)
- Potential to reduce anti-coagulation requirements
- Ability to address external driveline damage

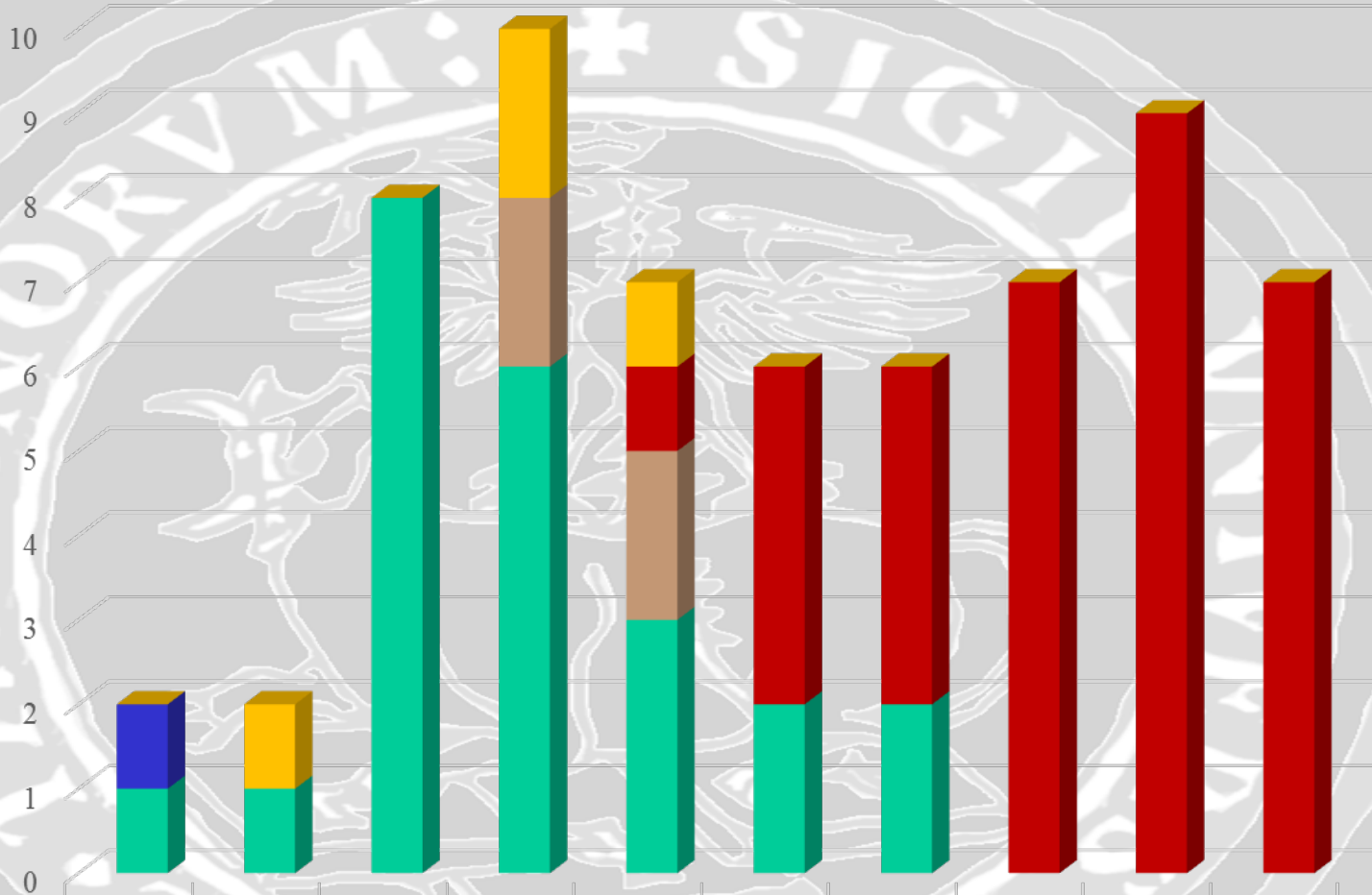
Program Status

- Design freeze on pump, motor, controller
- Design verification and pre-clinical testing underway
- Initiate CE Mark Clinical trials mid 2013 and US trial before the end of 2013

Minimally Invasive Approach



Long-term VAD- Università di Torino

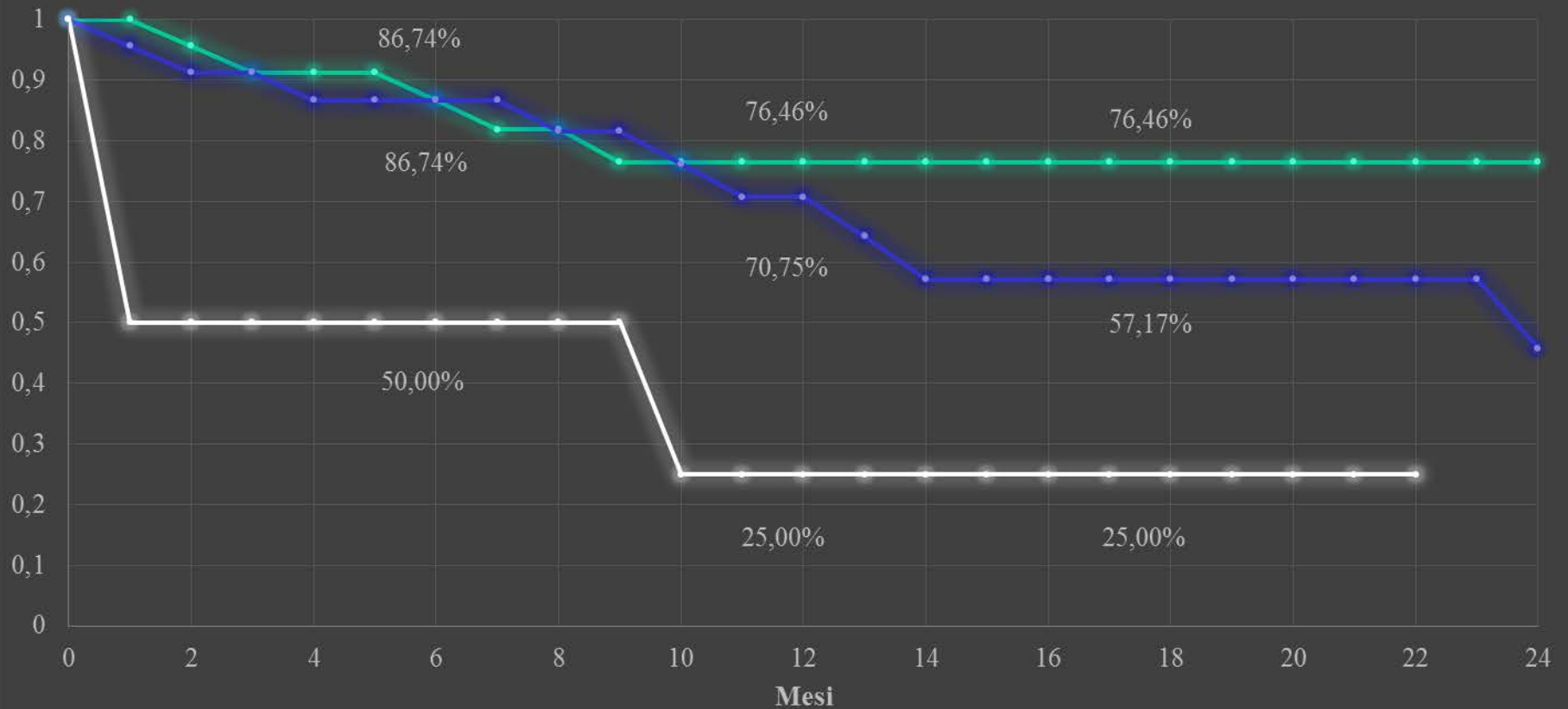


	2006	2007	2008	2009	2010	2011	2012	2013	2014	Ott-15
Excor	0	1	0	2	1	0	0	0	0	0
Heartware	0	0	0	0	1	4	4	7	9	7
Jarvik	0	0	0	2	2	0	0	0	0	0
HeartMate II	1	0	0	0	0	0	0	0	0	0
Incor	1	1	8	6	3	2	2	0	0	0



KM - LVAD per tipo (Censored per HTx/Recovery)

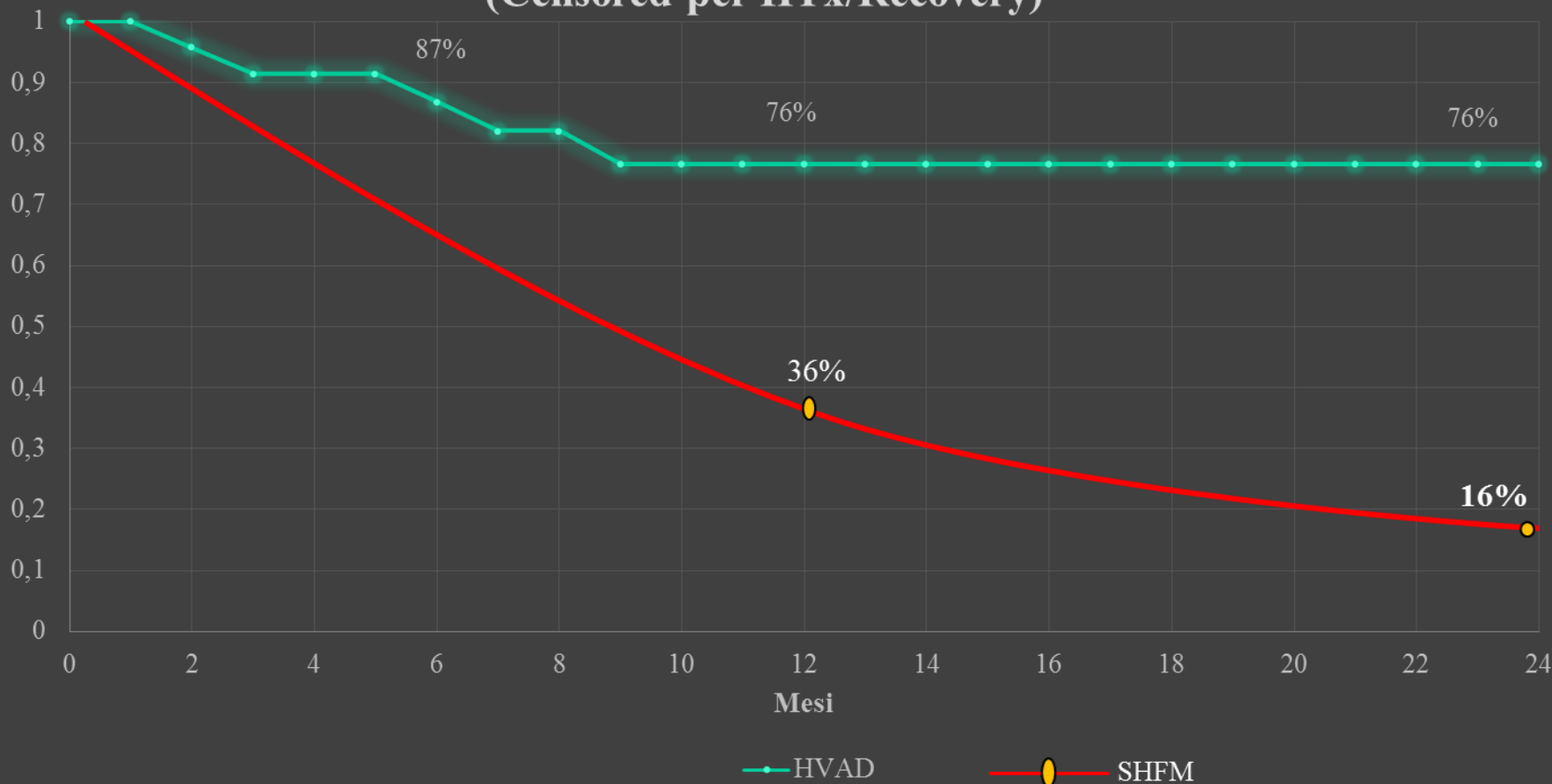
—●— HVAD —●— INCOR —●— Jarvik 2000





Follow-up medio 10.99 ± 12.21 mesi

KM HVAD vs Expected Survival SHFM
(Censored per HTx/Recovery)



EQ5D Dimension: Usual Activities

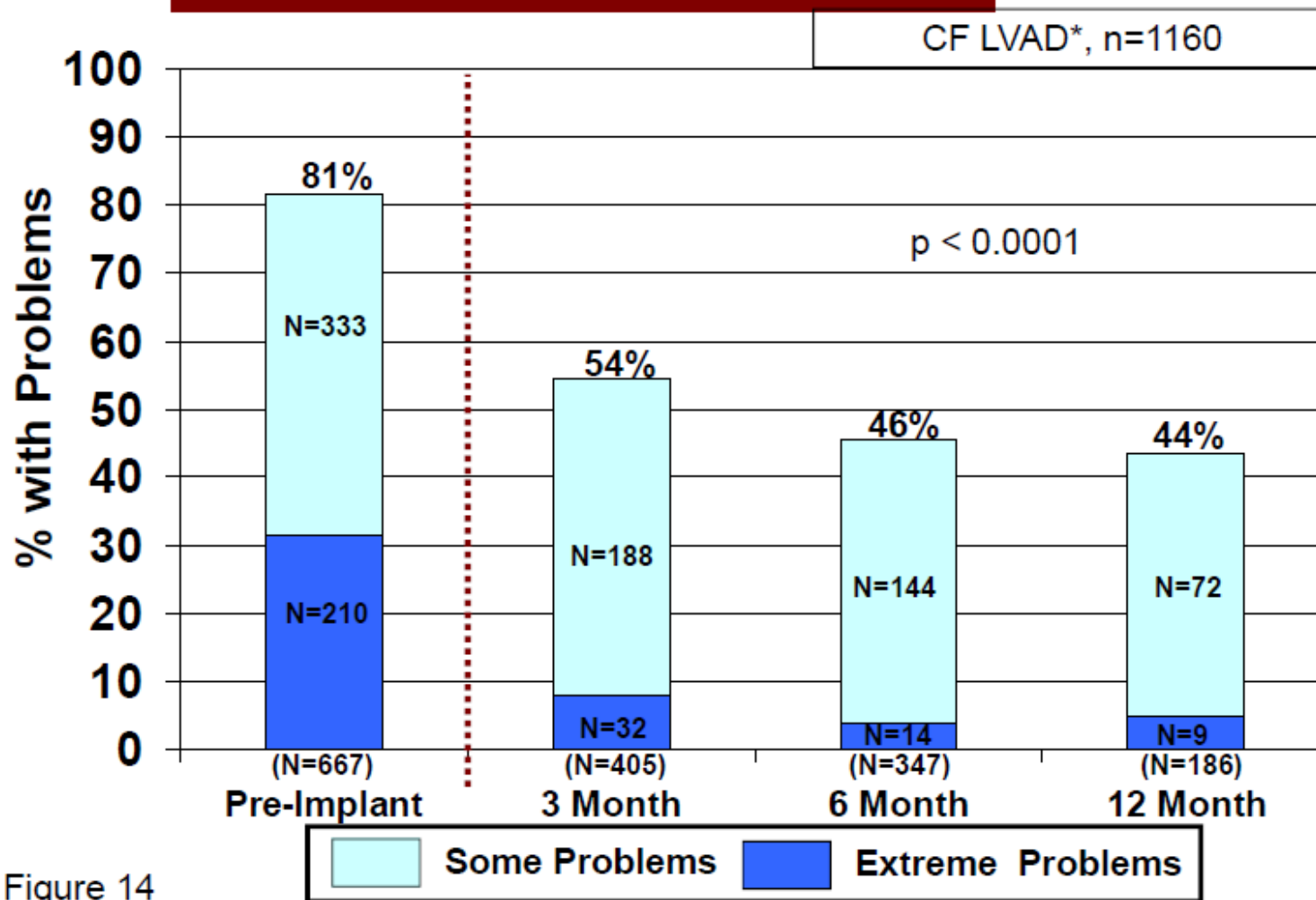
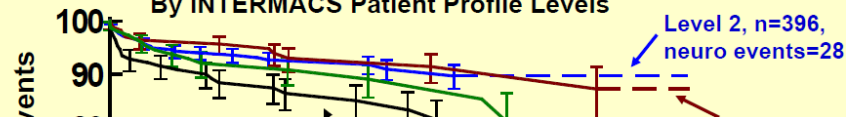
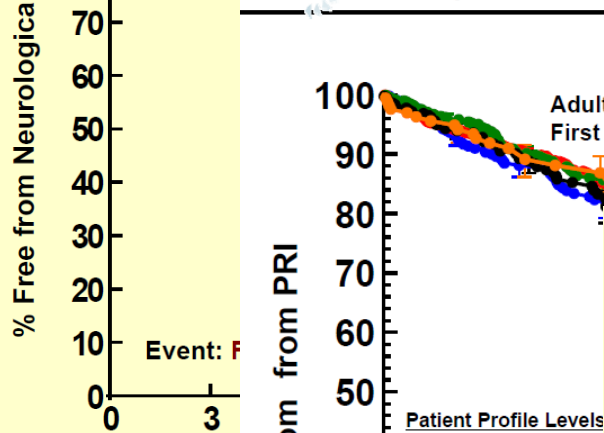


Figure 14

Adult Primary Continuous Intracorporeal LVADs: 896
By INTERMACS Patient Profile Levels

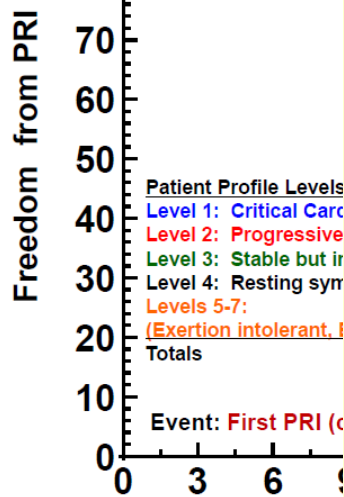


intermacs Implants June 2006 – March 2011: Pump-related Infection Analysis



Adult primary continuous LVAD (includes RVADs at same operation): n=2900
First PRI: n=428

INFECTION

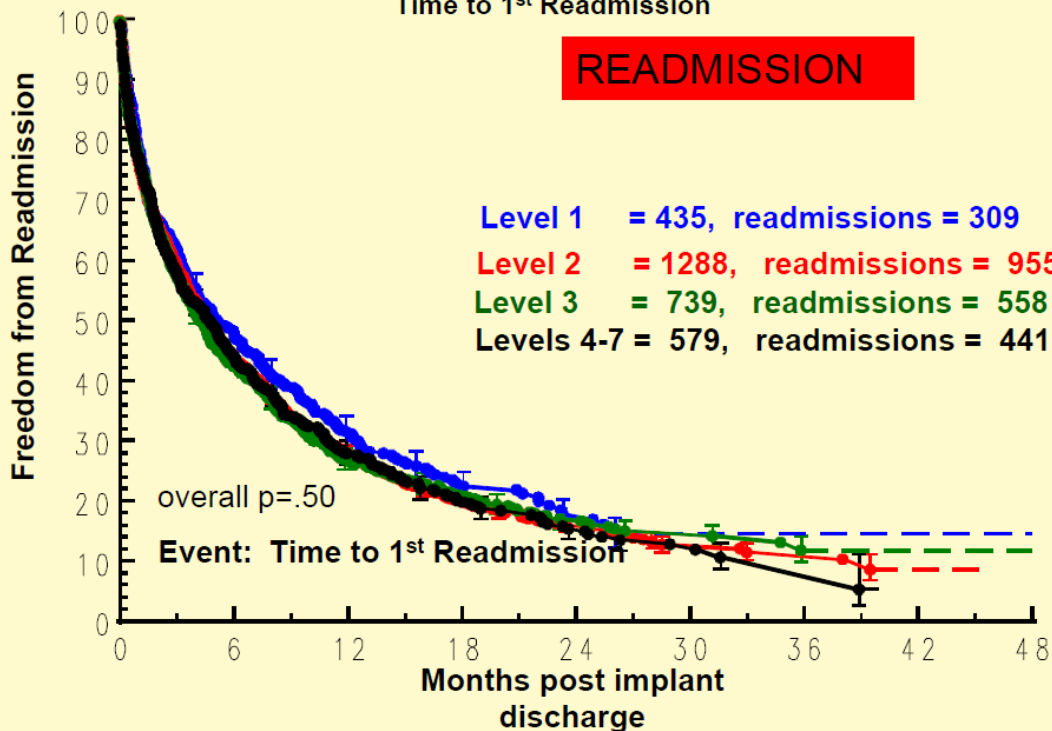


Patient Profile Levels
Level 1: Critical Care
Level 2: Progressive
Level 3: Stable but in
Level 4: Resting sym
Levels 5-7:
(Exertion intolerant, I
Totals

INTERMACS: April 21, 2008 – March 31, 2011 - Readmission

Adult Primary Continuous Flow LVAD(+/-RVAD), n=3041*
Time to 1st Readmission

READMISSION



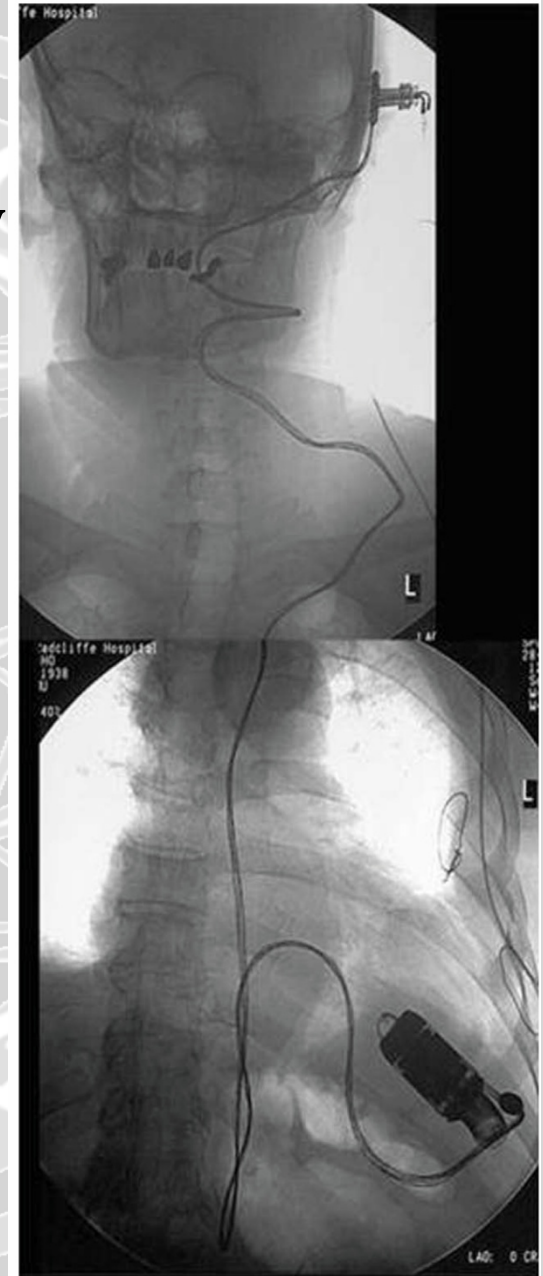
* Patients discharged from index hospitalization

Retroauricular pedestal



**Improves Quality
of life**

**Reduces
Infections**

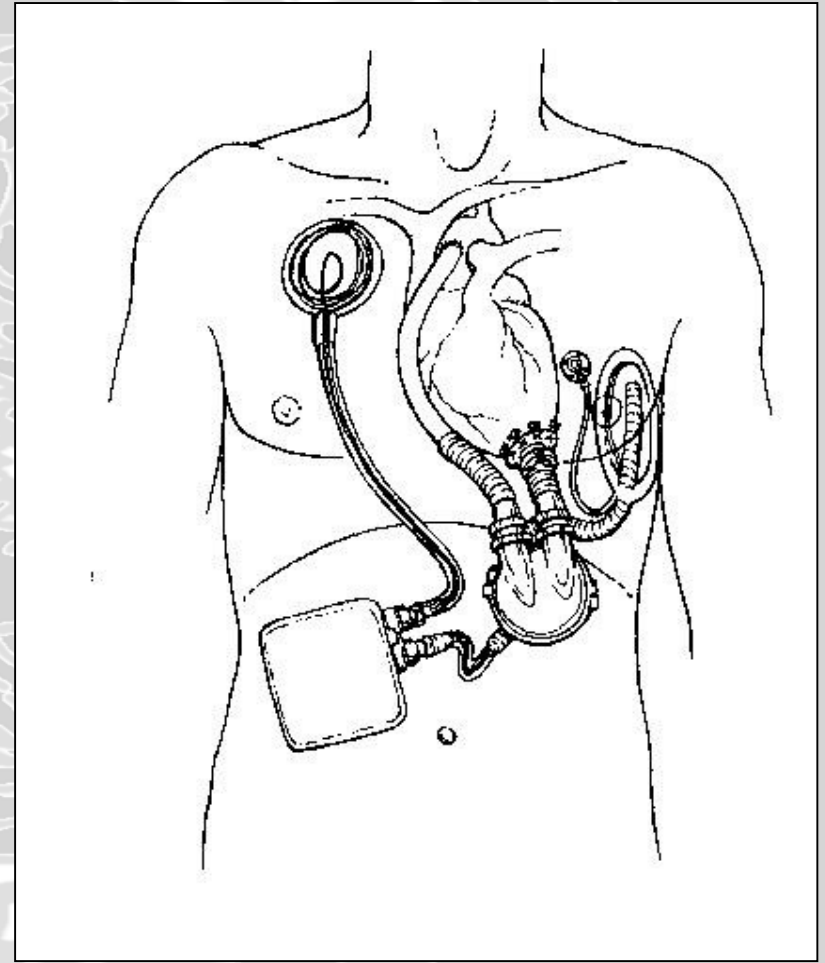
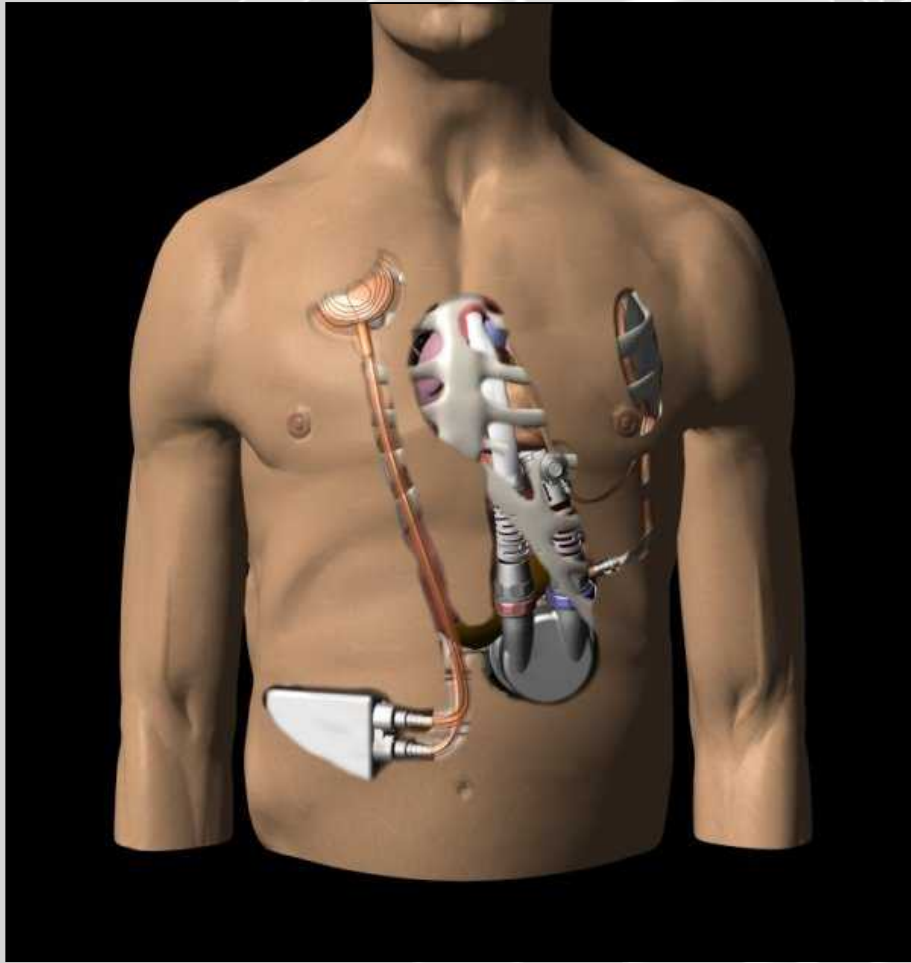


Better Quality of Life...

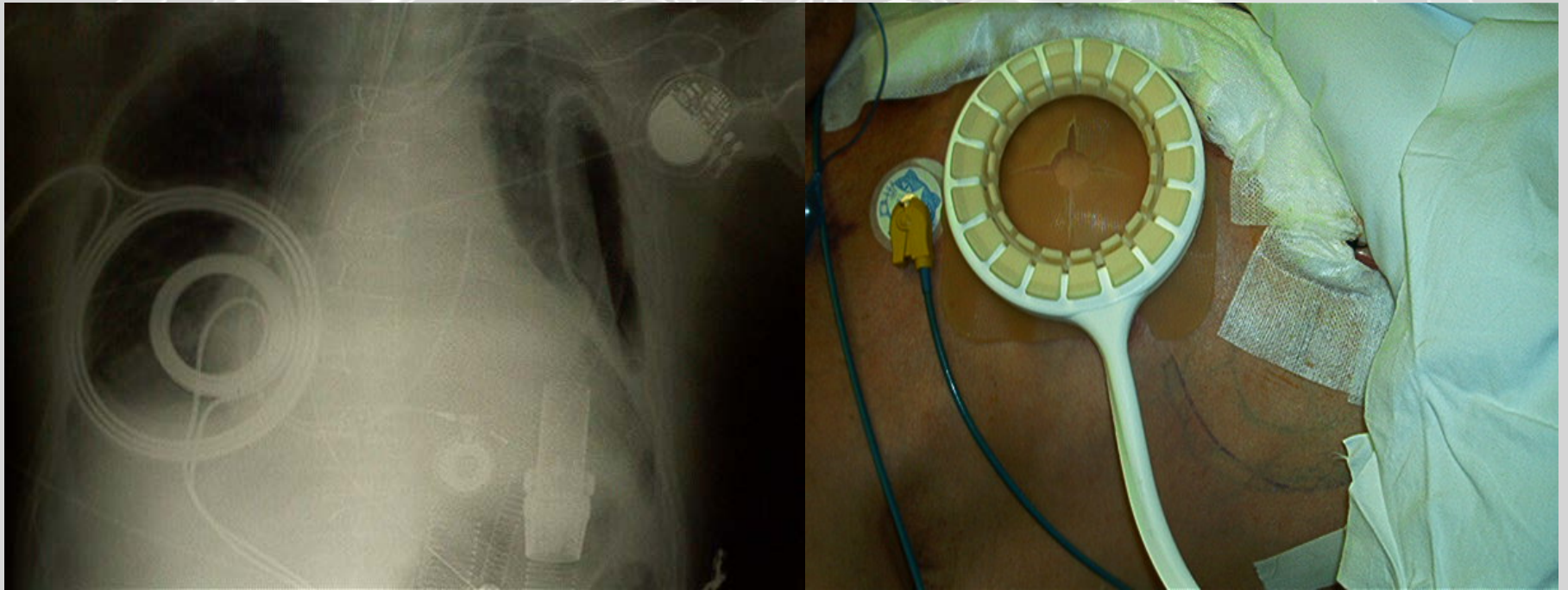


Totally implantable LVAD

The Lion Heart



TET: Transcutaneous Energy Transmission

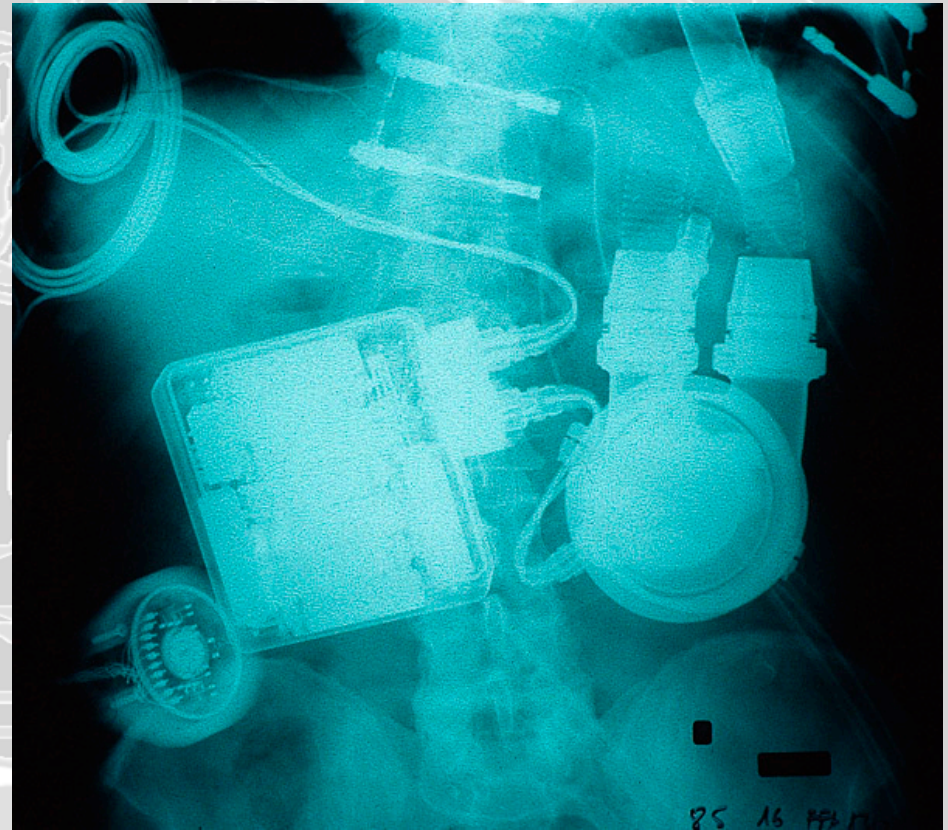
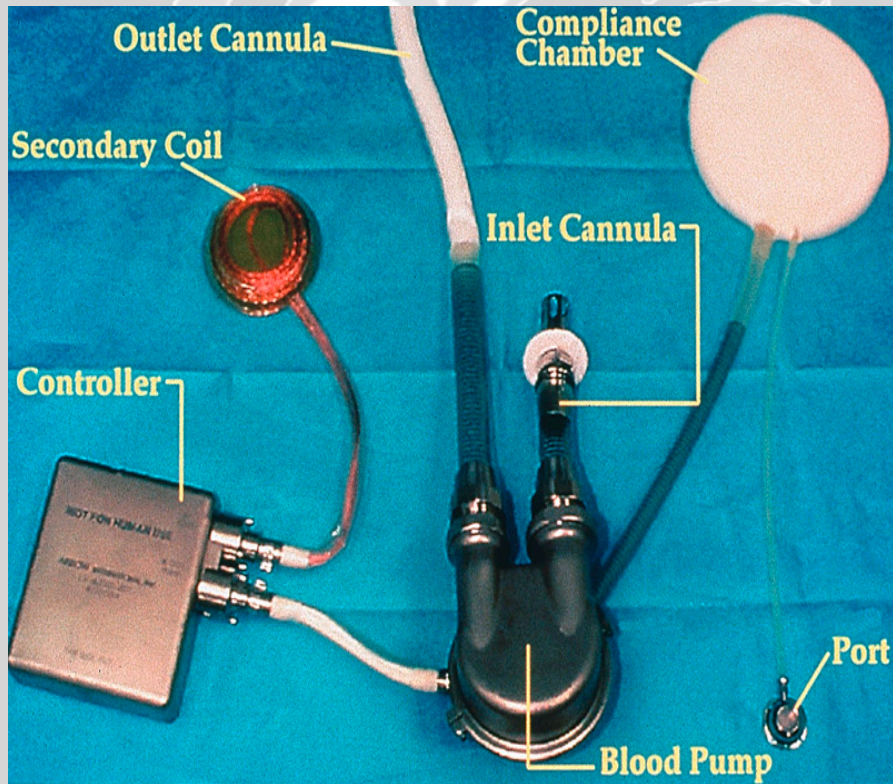


LionHeart PV-01



Pre OP patient preparation

LION HEART

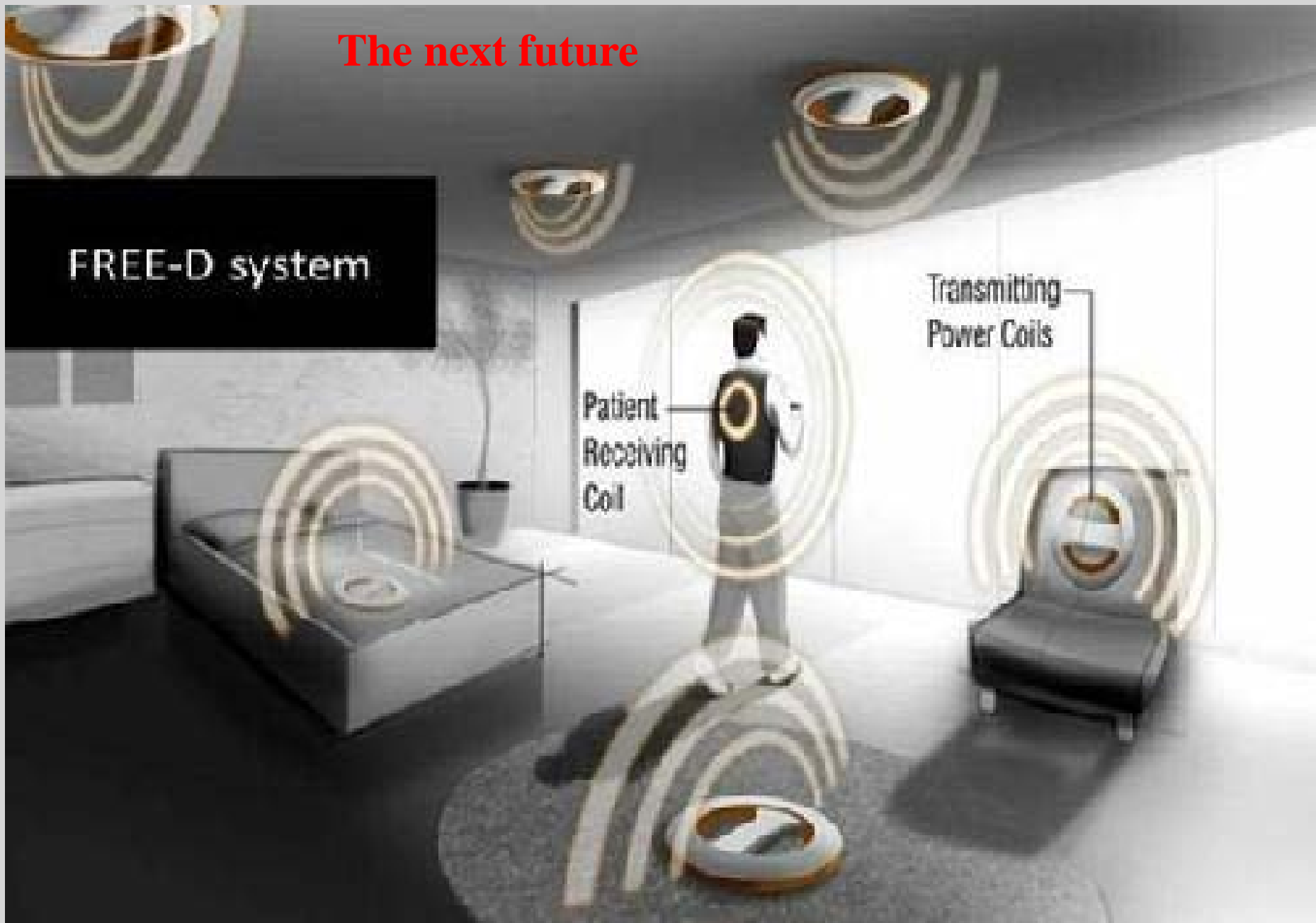


The next future

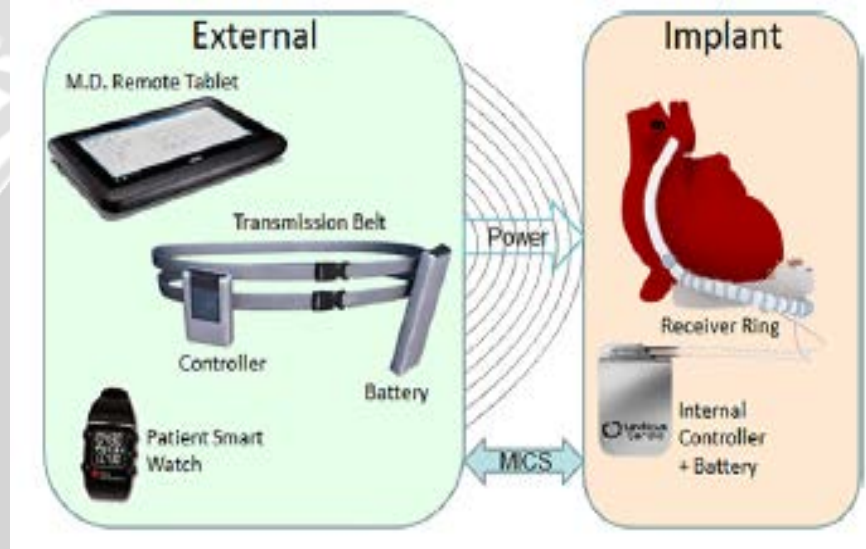
FREE-D system

Patient
Receiving
Coil

Transmitting
Power Coils



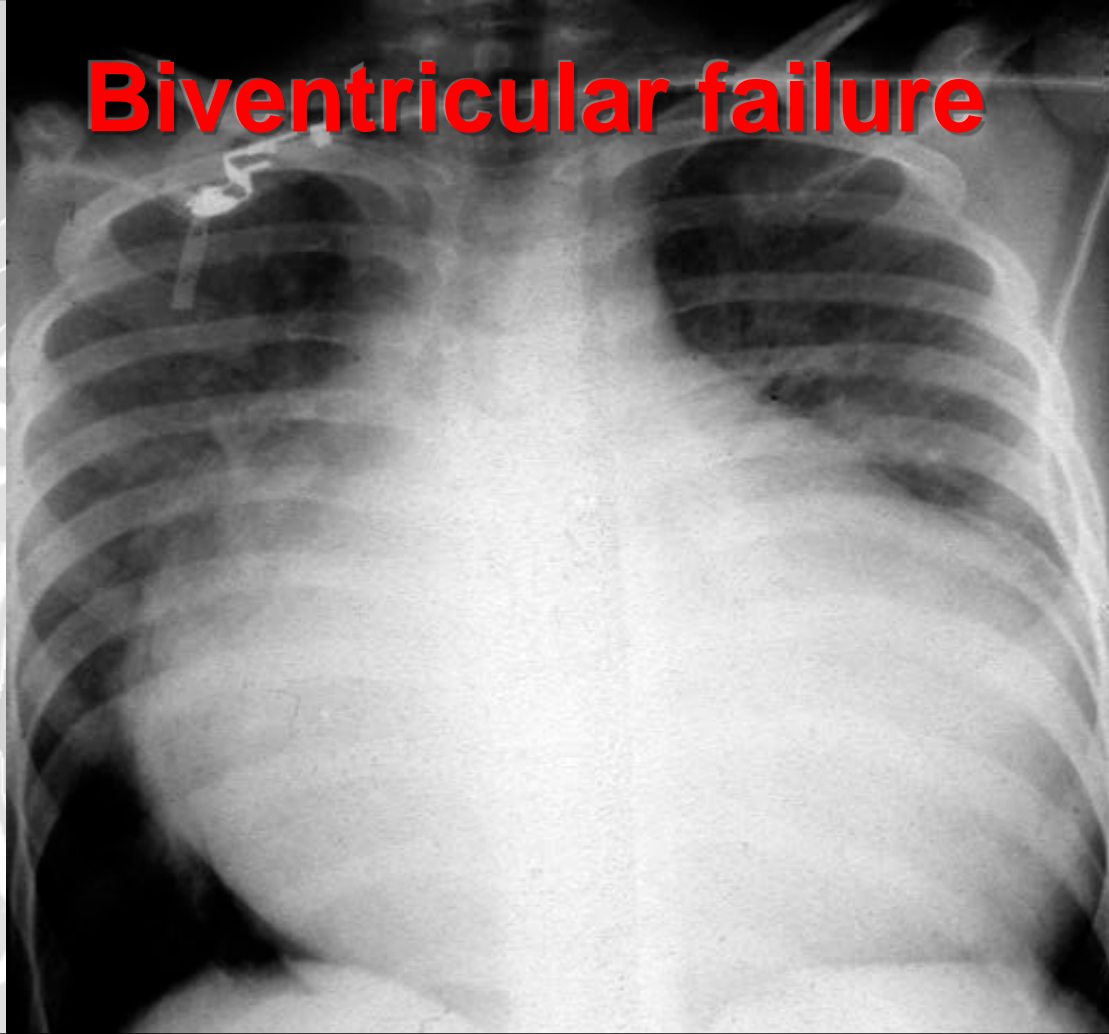
Transcutaneous Energy Transmission: Jarvik Heart



May 2, 2013 -Leviticus Cardio, recently performed a successful animal surgical trial using its wireless coplanar energy transfer system (CET) for ventricular assist devices (VAD).

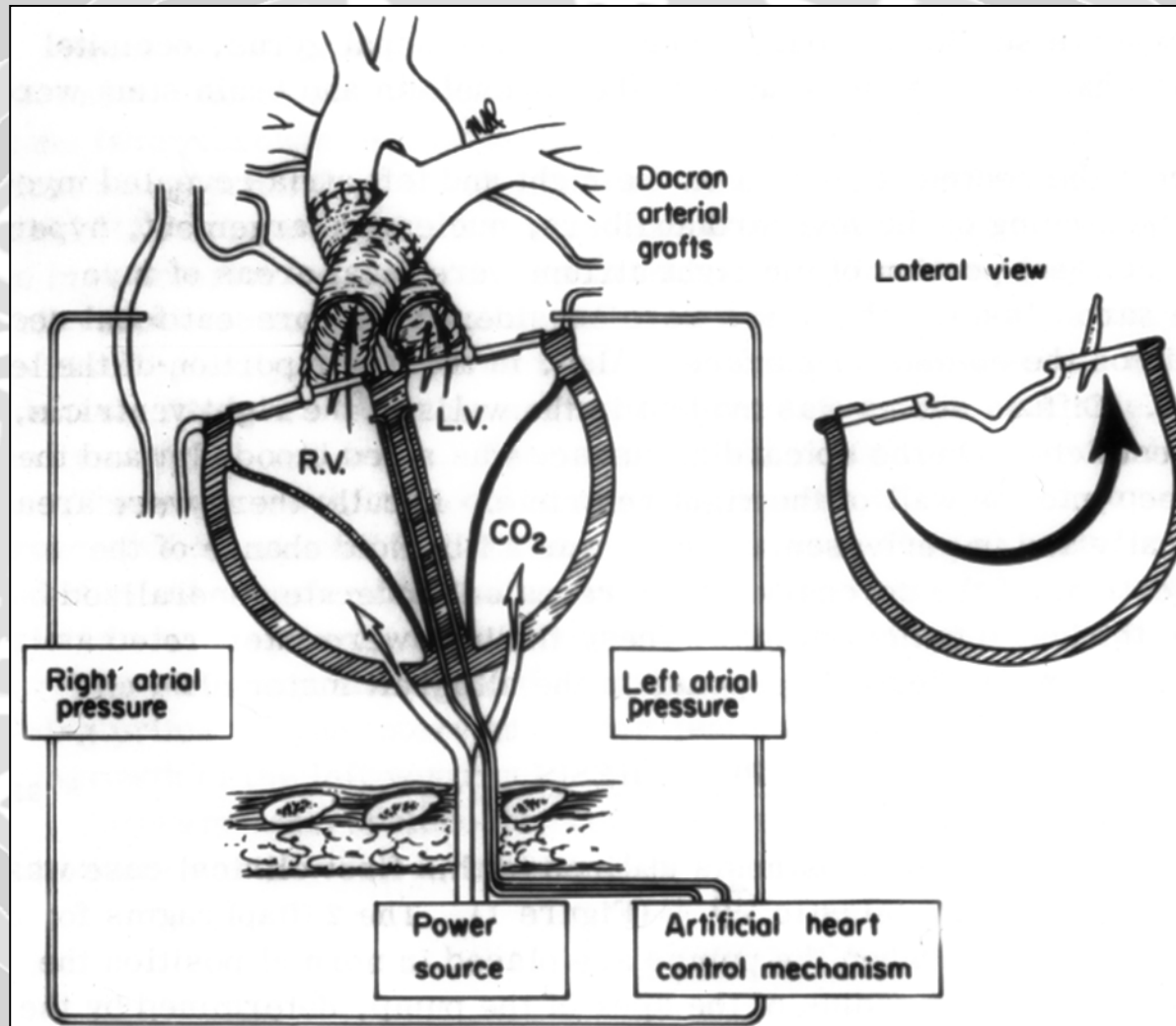
The surgery was performed at Assaf Harofeh Hospital using **Jarvik Heart VAD**. The CET system performed the **energy transfer** to the animal body and **controlled the VAD** pump operation.

Biventricular failure



- ***Age (over 65 years)***
- ***Comorbidities***
- ***Severe Pulmonary Hypertension***
- ***Cardiac tumors***

TOTAL ARTIFICIAL HEART TAH



A PIONEER OF THE CLINICAL USE OF MCSS

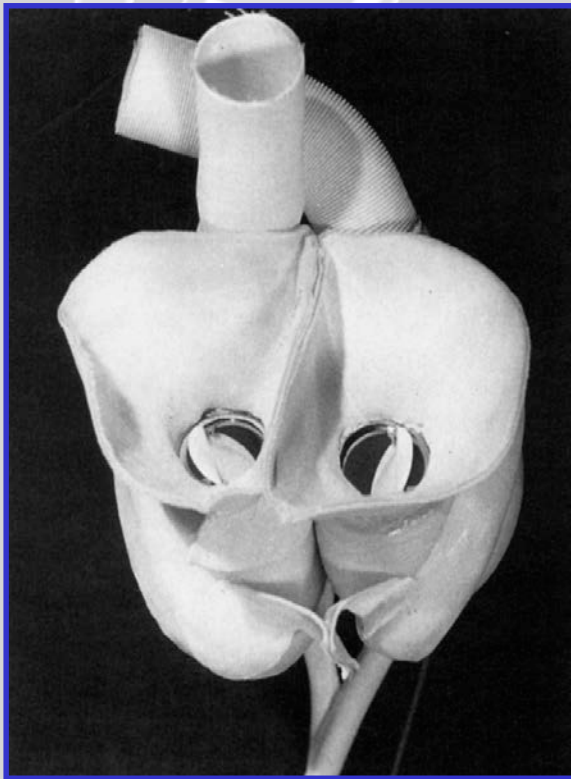
First TAH--Bridge to Transplant 1969
(April 4), Texas Heart Institute, Houston, Texas

Pat. 47 years old H.K

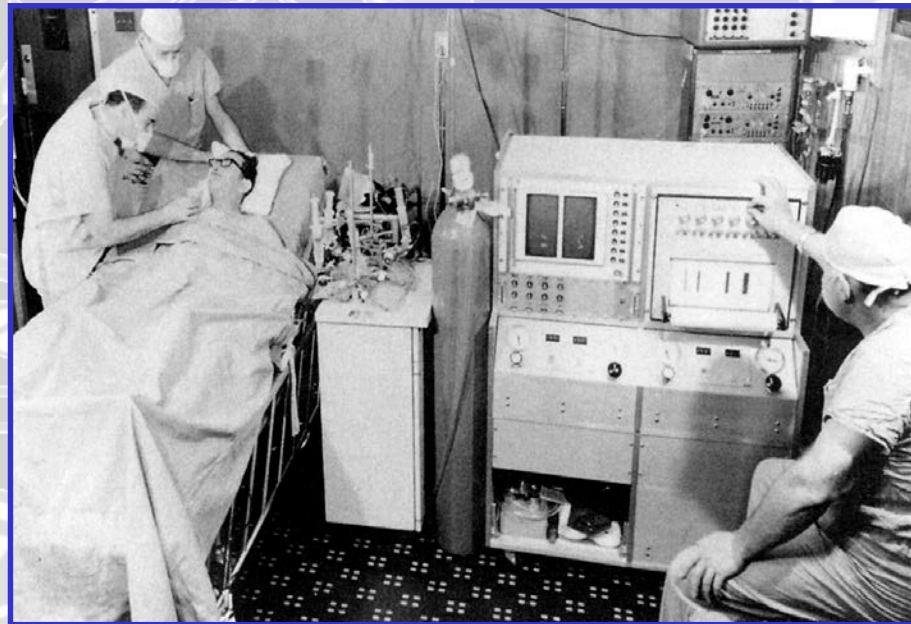
LCO after LV aneurysm resection

MCS-64 h

Died 32 h after Htx



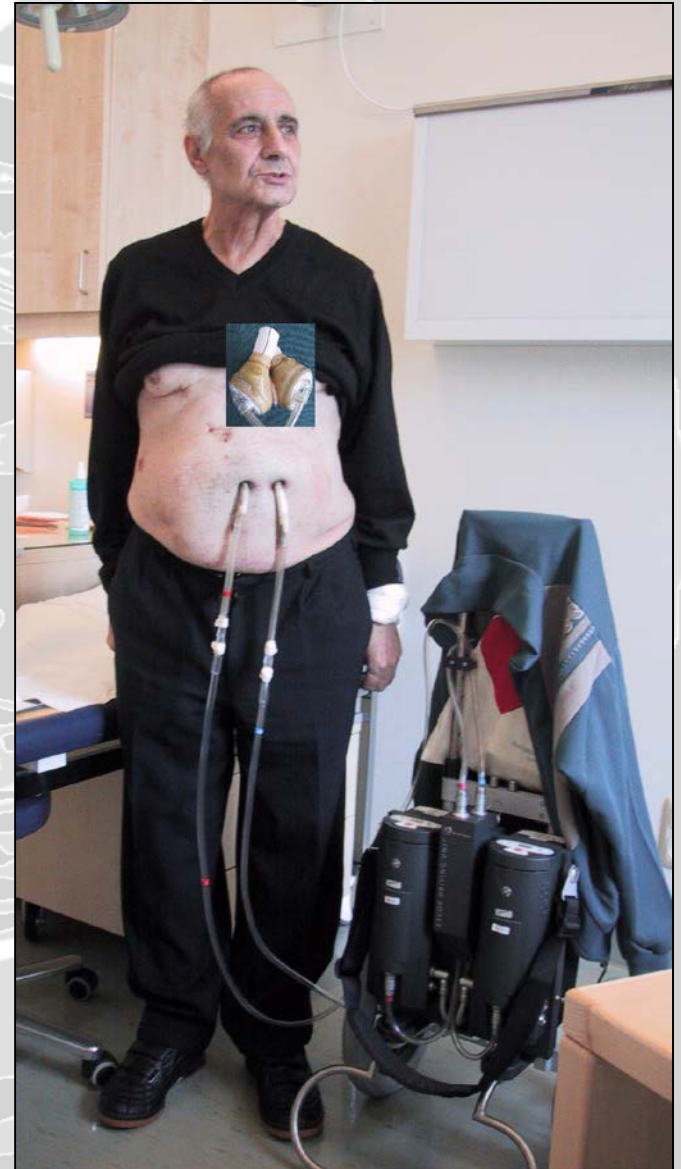
Liotta's artificial heart



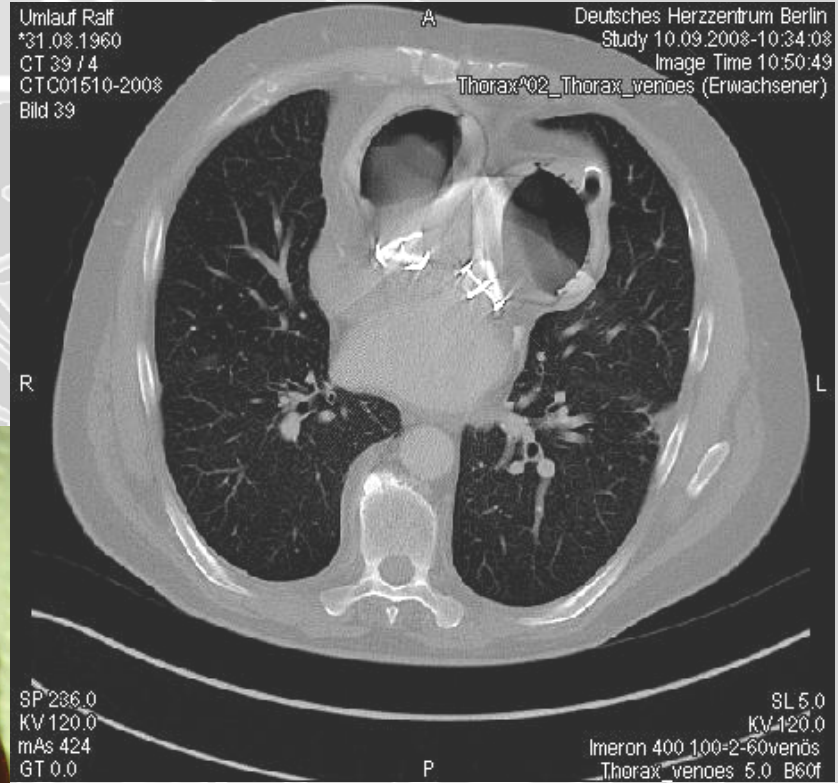
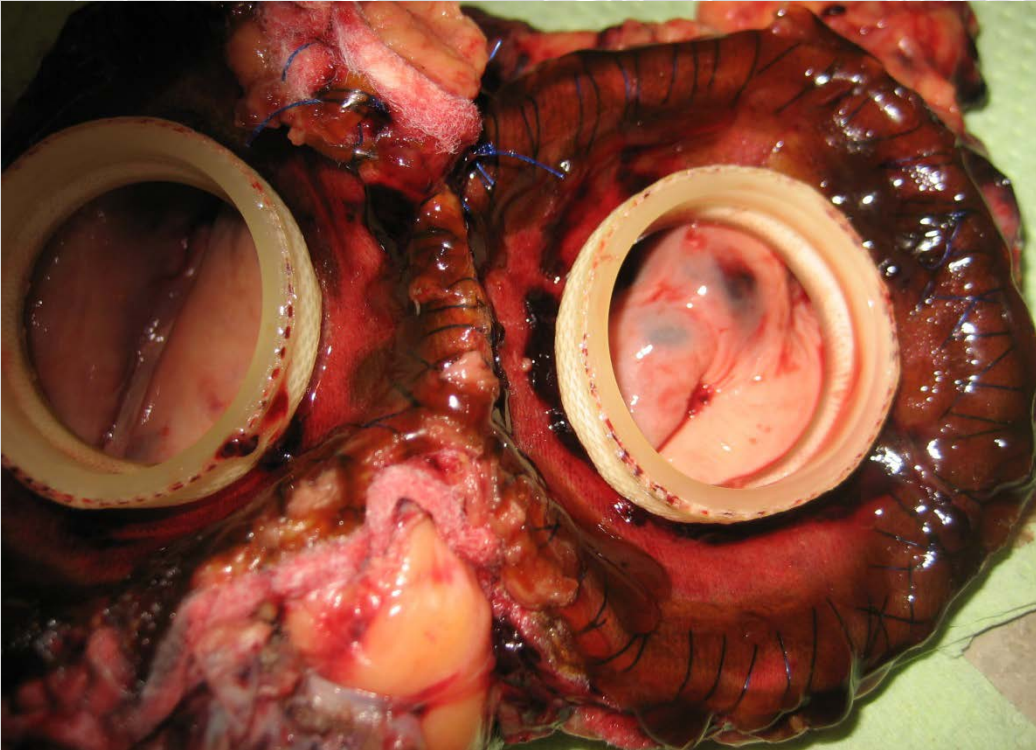
Denton Cooley and Dominigo Liotta

1969

CardioWest Total Artificial Heart

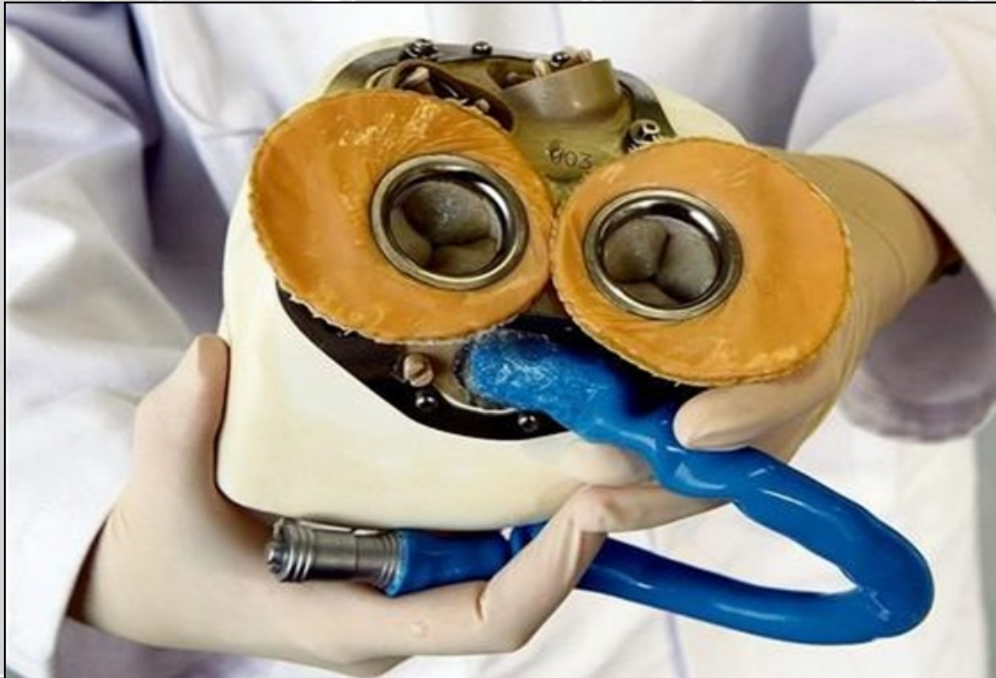
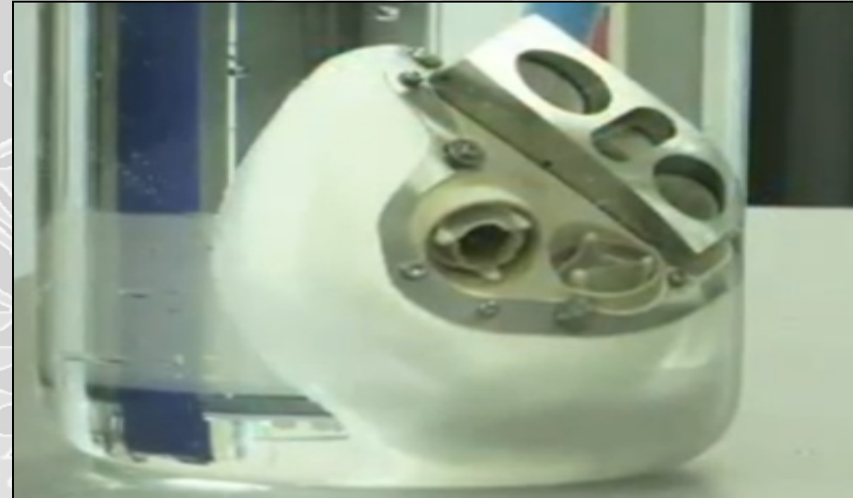
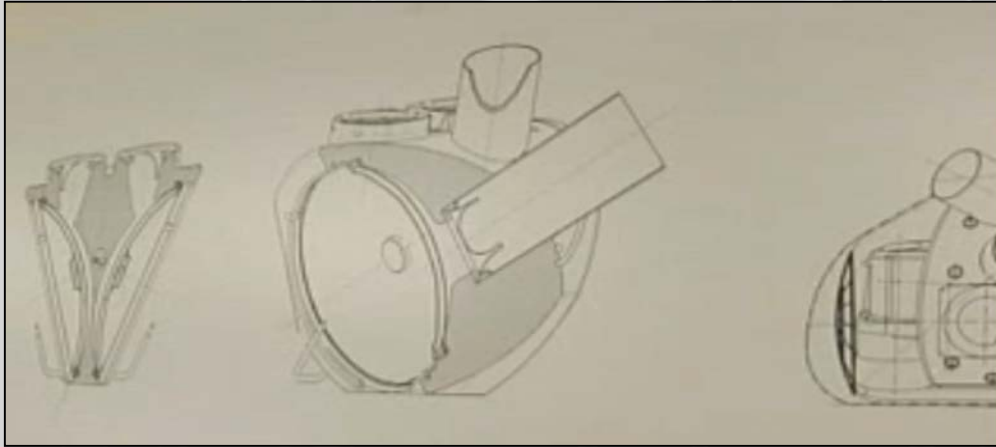


CardioWest TAH



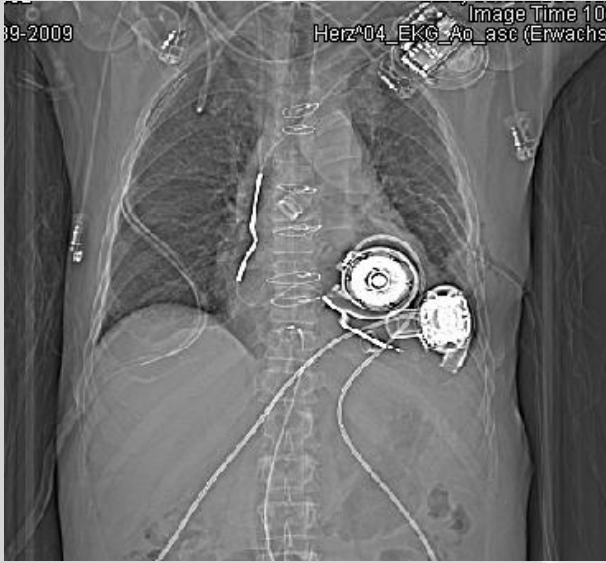
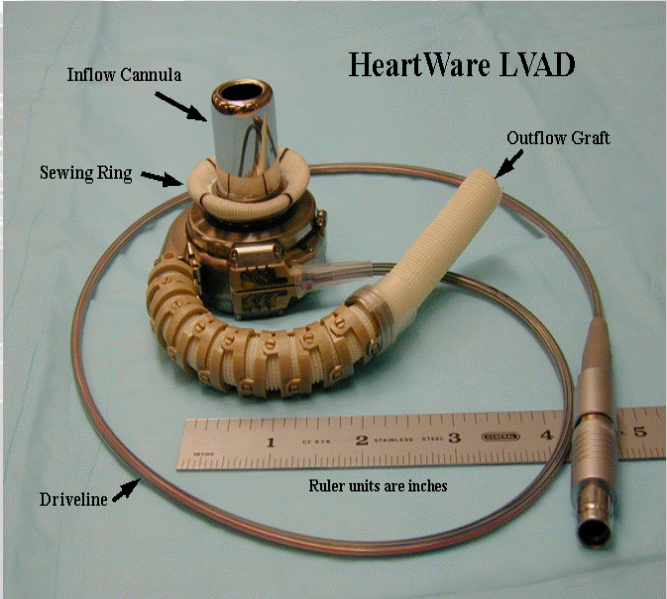
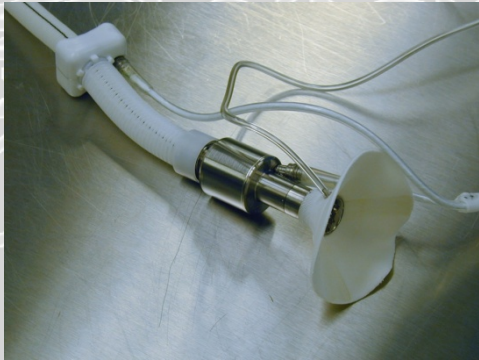
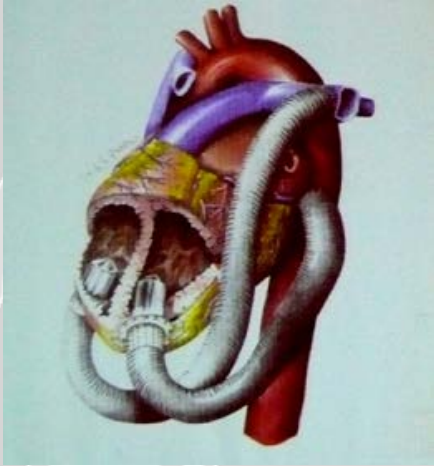
CUORE BIOLOGICO

CARMAT 2008 TAH

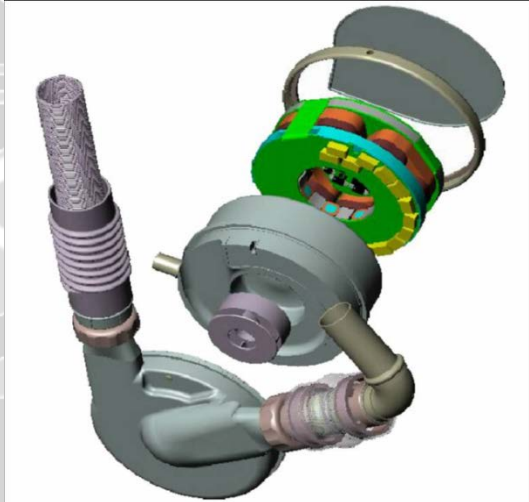


Professeur Alain Carpentier
Cardiac Surgeon, European Hospital

ROTARY PUMPS AS TOTAL ARTIFICIAL HEART??



FIRST STEP
BIVENTRICULAR
HEART SUPPORT ??



Right Ventricle



BANDING of the
Pulmonary Outflow
Graft (25%)

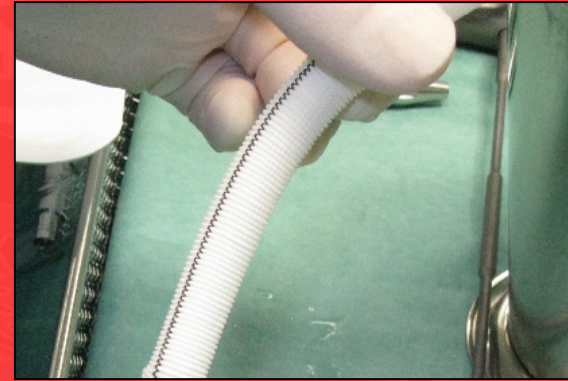


Reduction of Inflow
Cannula Length

**HeartWare LVAD
Modification for Clinical RVAD**

DHZ Berlin Prof. HETZER Solution

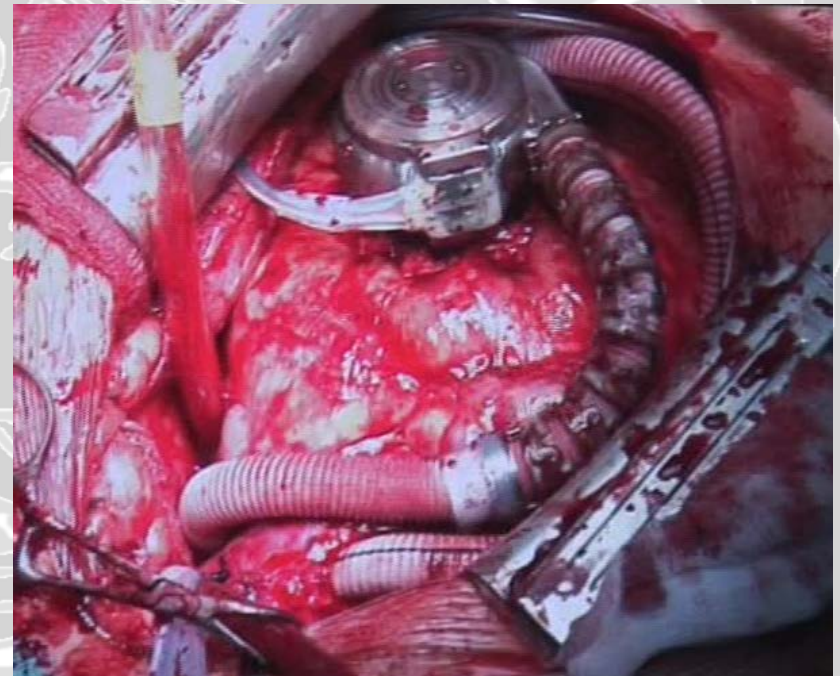
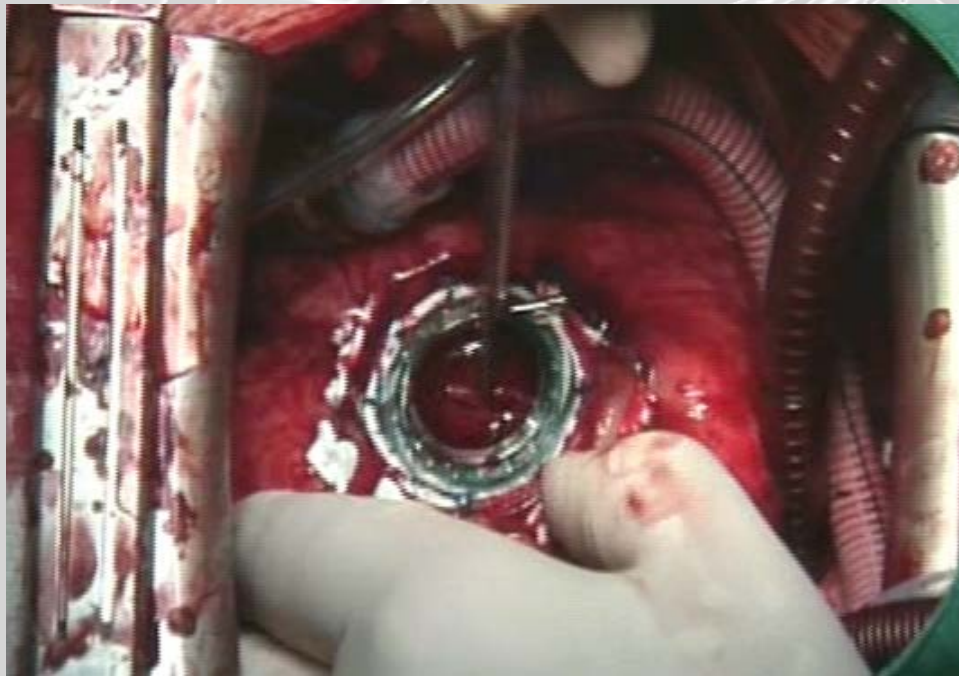
Left Ventricle



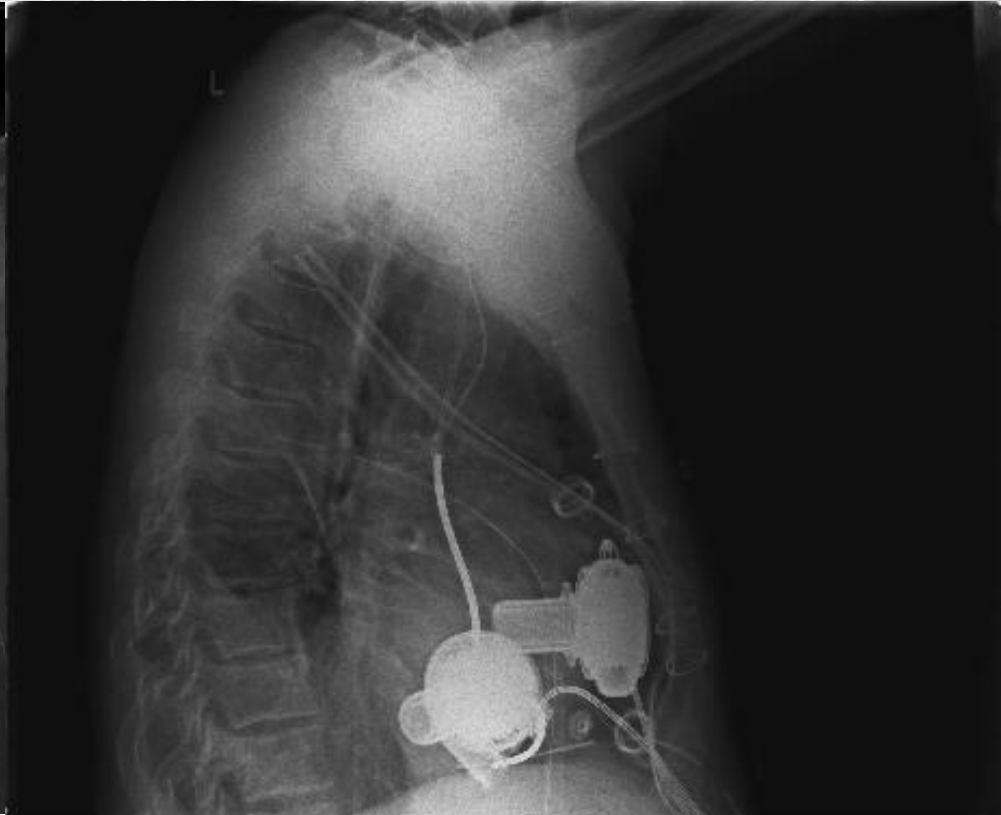
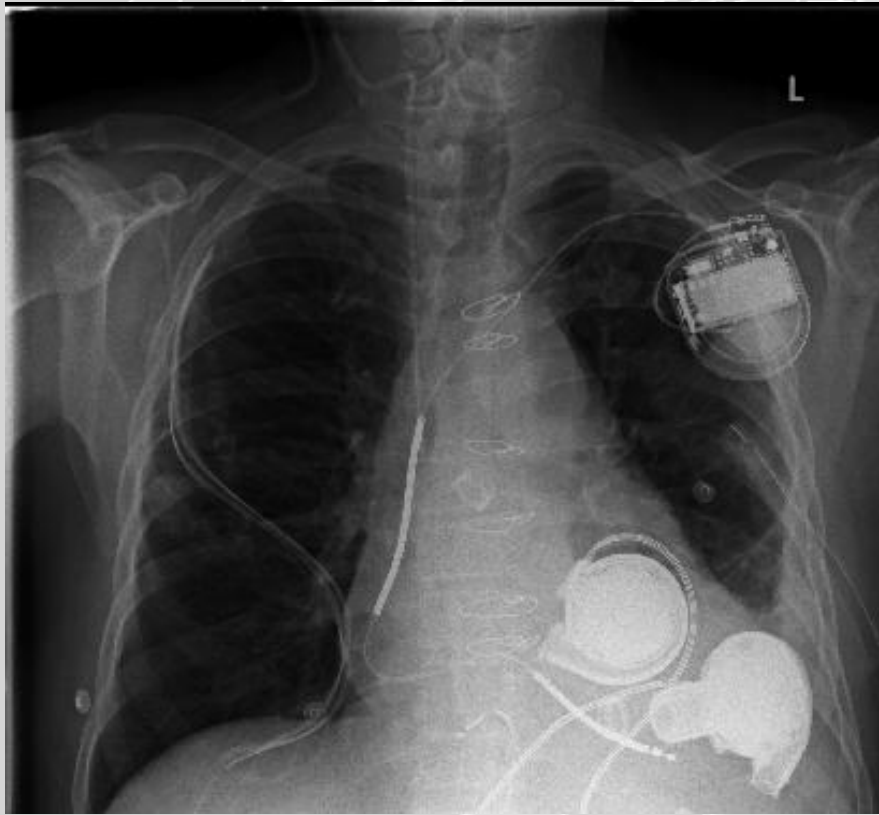
HeartWare LVAD

DHZ Berlin Prof. HETZER Solution

Biventricular permanent continuous flow devices (*Berlin solution*)



Biventricular permanent continuous flow devices (*Berlin solution*)





Future directions...

IDEAL VAD

- **Biocompatible**
- **Reduced dimension**
- **Reliable** (*10 million beats/years o 4 billion cycles/years*)
- **Low energy requirements**
- **Easy to implant and.....to explant**
- **Allowing the discharge of the patient**
- **Cheap.....**

Future Trends

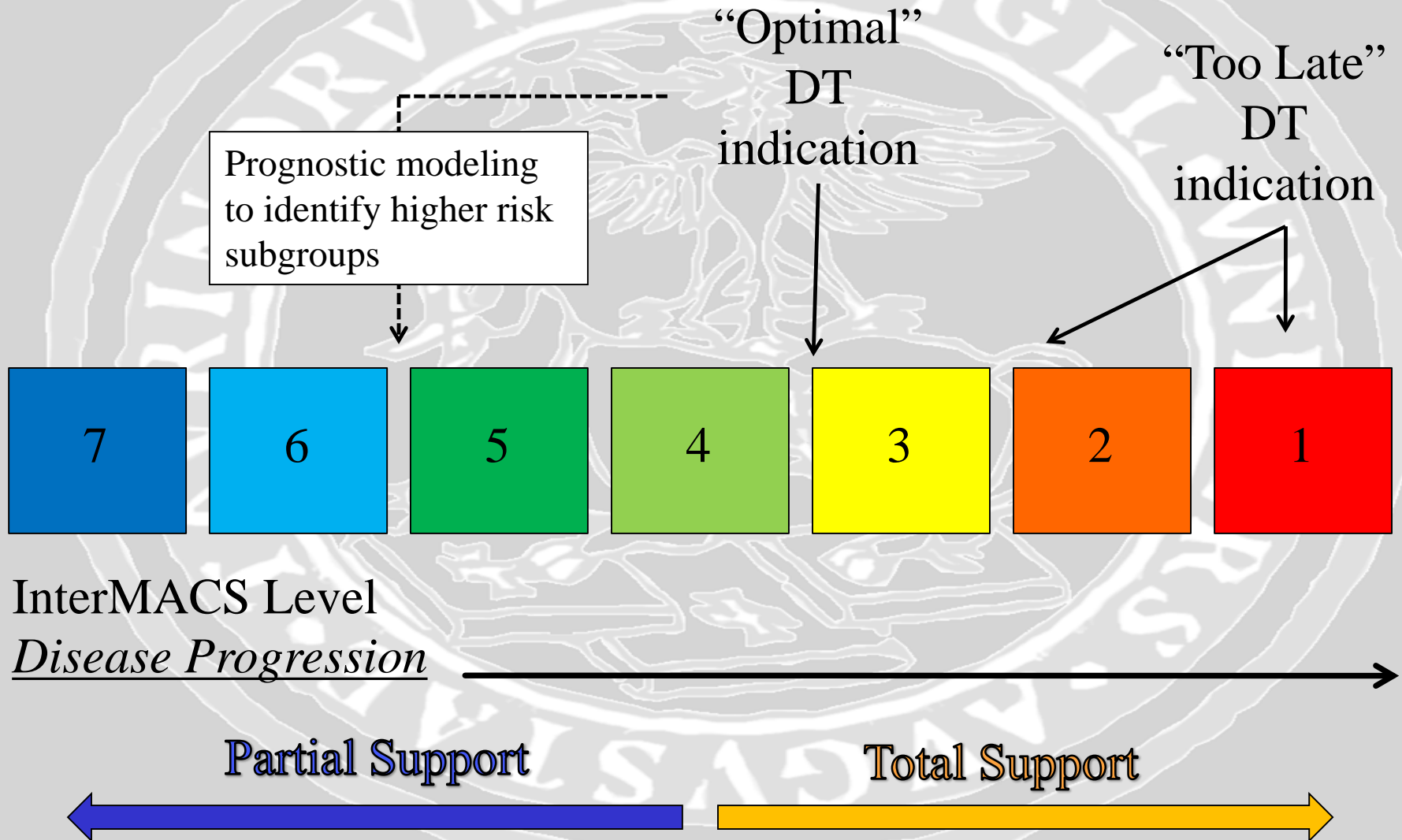
beyond 2020

- **Early support/Parzial support**
- **Percutaneous implantation**
- **Wireless power**
- **Simplified management (like PM/ICD)**



.... like a pill....

Optimal Timing of LVAD Implantation



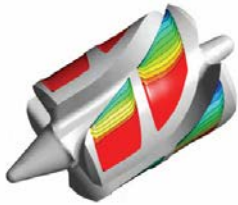
Heartware MVAD



Miniaturization.....

Heartware - MVAD

- Left thoracotomy or sternotomy
- 1 - 10 liters per minute of flow (full range of patients)
- Exceptional fluid dynamics
- 1/3 the size of HVAD



Intracorporeal BVADs for DT

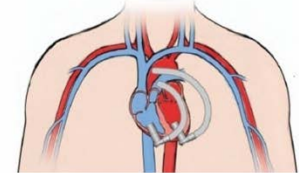
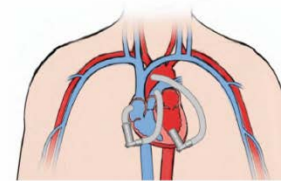
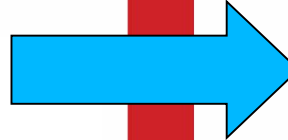
- **Size** → *less invasive implant*
 - **Right sided support: RVAD**
 - **Integrated BVAD—one controller**
- In future may allow pts with RVF/sicker pts



HeartMate X



Heartware MVAD



HeartMate X

Versatile, Dramatically Downsized Chronic Support Platform Technology

Product Design



- Leverages core HeartMate II technology
- Versatile platform, capable of providing partial and full support (1-8 L/min)
- High-efficiency motor and hydraulics

Expected Benefits

- **Dramatic size reduction**
 - Rapid, less invasive implant
 - Versatile cannulation options
- **Meets needs of expanded patient pool**
 - Earlier-stage patients
 - RVAD / BiVAD population
- **Low power consumption**
 - Potential for smaller external batteries and components

Program Status

- Two hydraulic configurations in development
- Preclinical studies underway
- Evaluating multiple surgical access and cannulation options

LVADs development

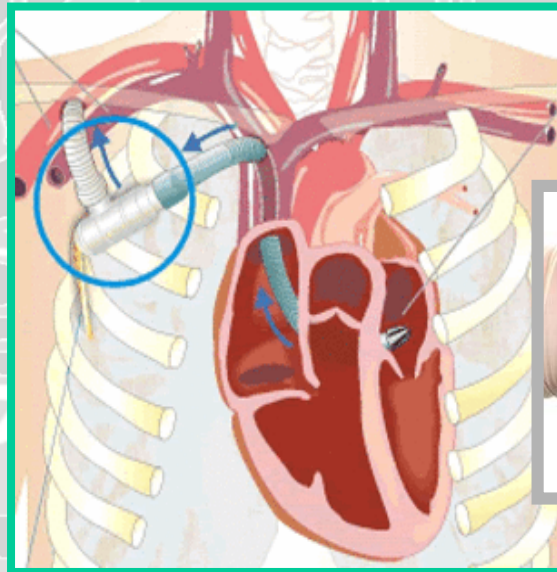
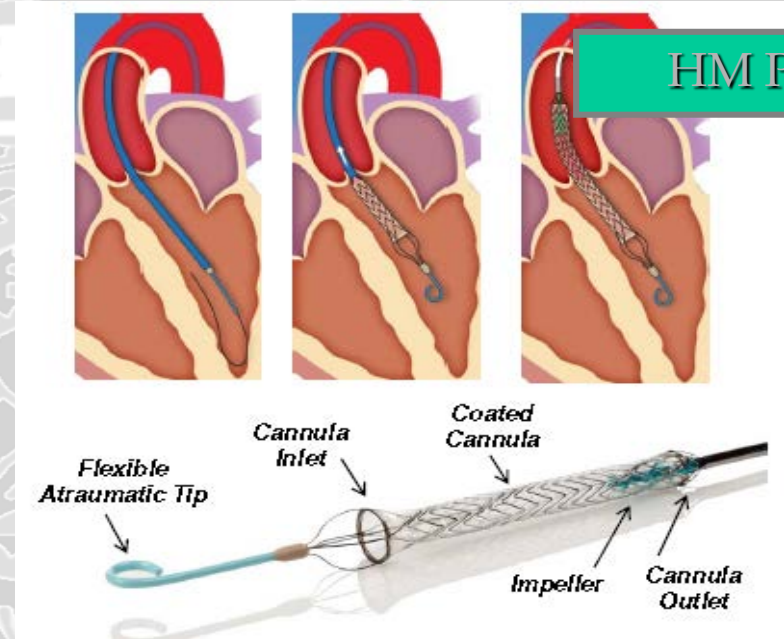
5th Gen



- Percutaneous VADs

- HeartMate PMP
- Reitan Catheter Pump System
- Aortix device
- Symphony

- Partial Circulatory Support



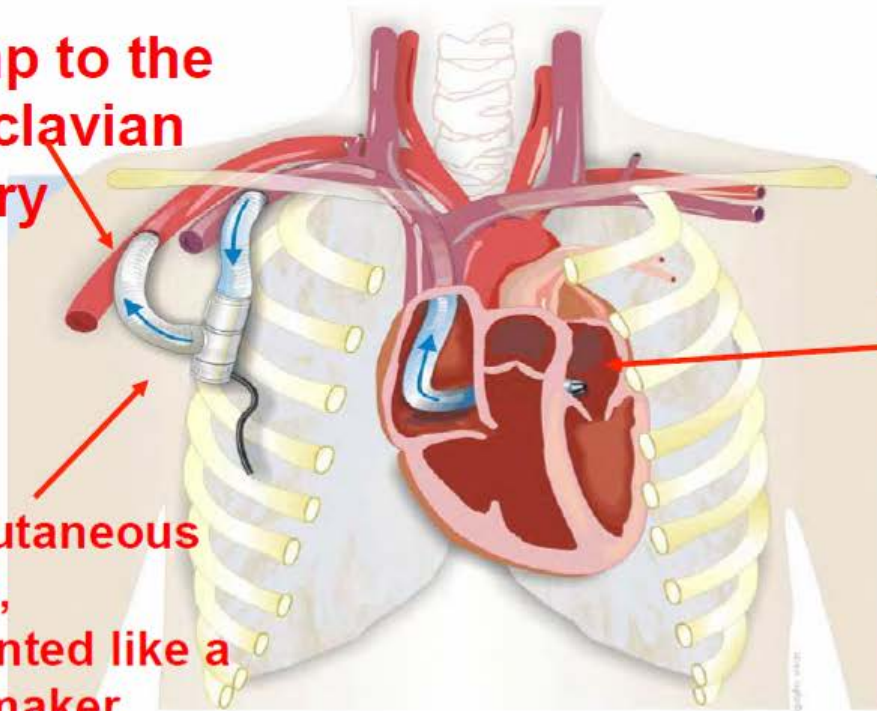
Circulite



Partial support – minimally invasive

Pump to the
Subclavian
Artery

Subcutaneous
pump,
implanted like a
pacemaker



Take Blood
From LA



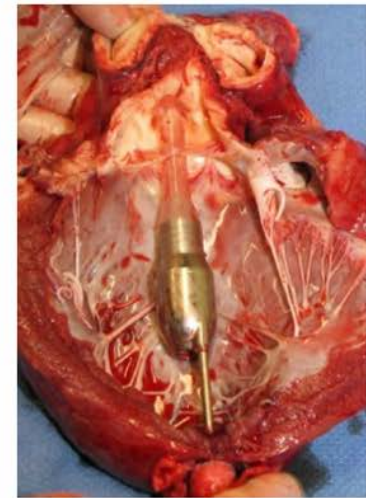
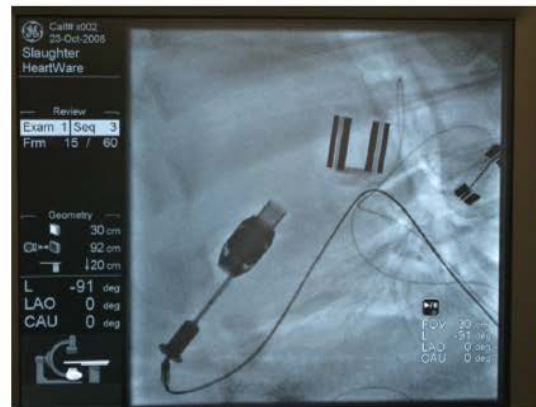
CircuLite



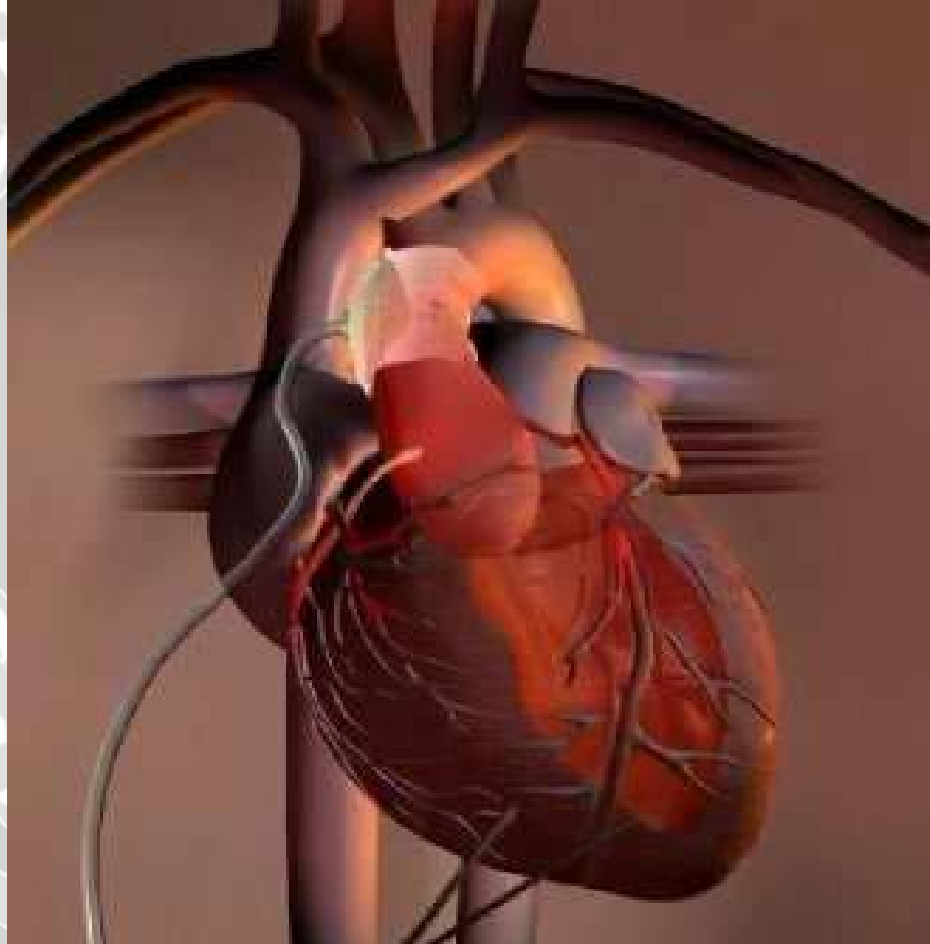
Transapical devices

“Longhorn”

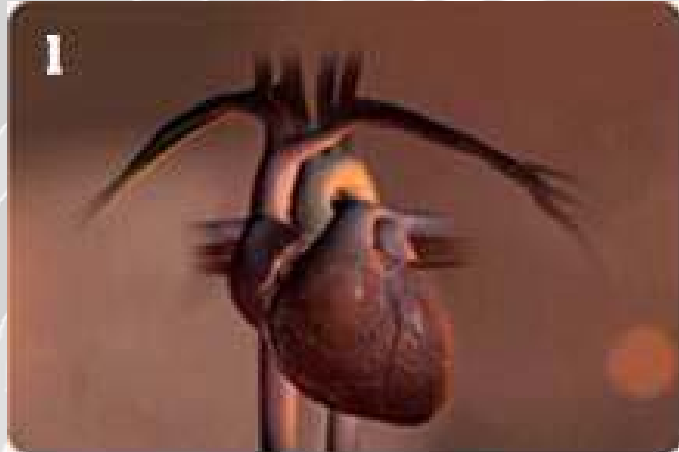
Transapical placement via subcostal incision
Inflow and motor in the LV, outflow in the ascending aorta
Up to 7 liters per minute of flow
“30 Minutes Skin to Skin”



No blood contact device C pulse

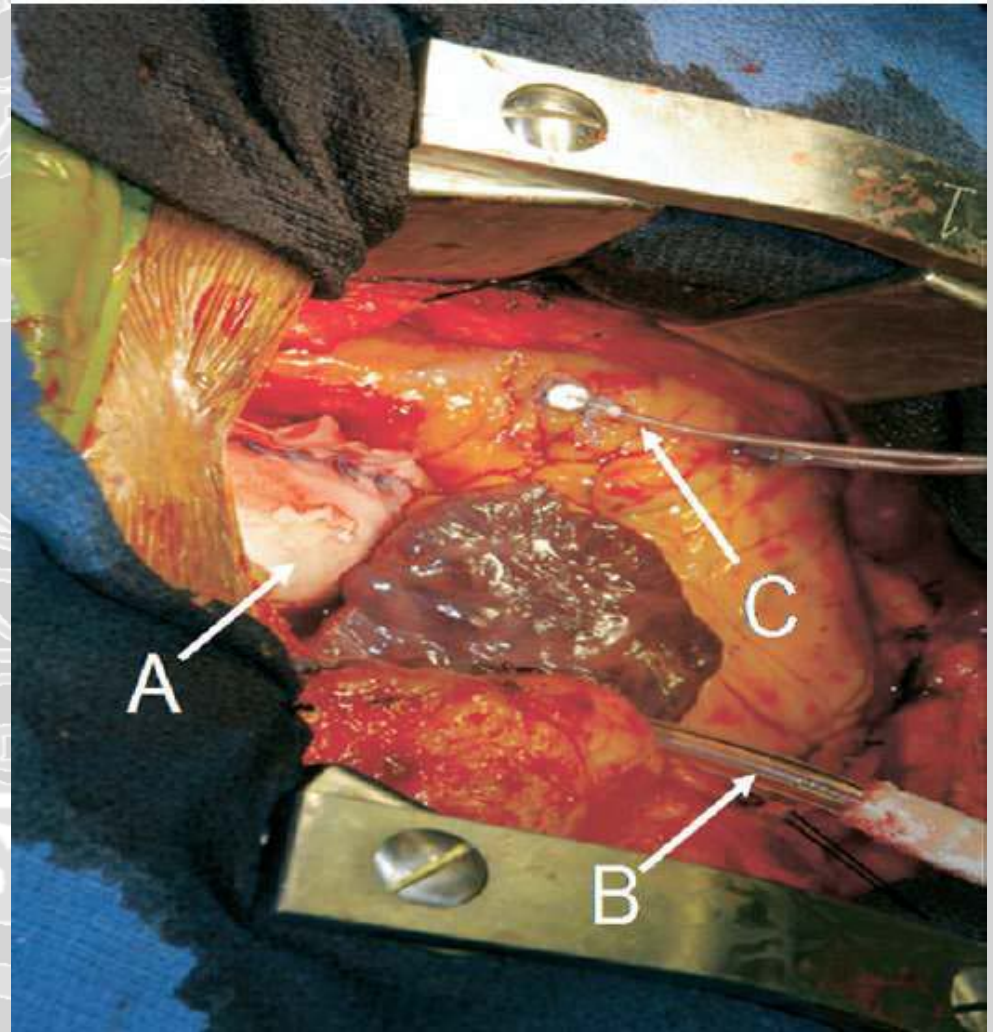


C pulse



C pulse device in place

A=Cuff
B=Gas line
**C=Epicardial
EKG sensing
Lead**




Conclusions

- **Emerging new technology smaller & lighter (potentially better performance)**
- **Implantation techniques improving “less invasive” approaches (percutaneously without the need for an open surgical procedure)**
- **External components smaller, TETS in development**
- **Current & future developments should continue to reduce adverse events and improve survival / overall QoL**
- **LVAD use in a greater number of pts**
- **LVAD cost-effectiveness evaluation for decision about resources allocation**



New patient's population!!!



“Eventually, as cardiac support or replacement devices become smaller, more durable, and less obstrusive, they may become as conventional and common place as pacemaker are today”

Frazier OH, 2000



1984



2014

«...it is very difficult to foresee the future...»



Steven Spielberg and Robert Zemeckis
1985

