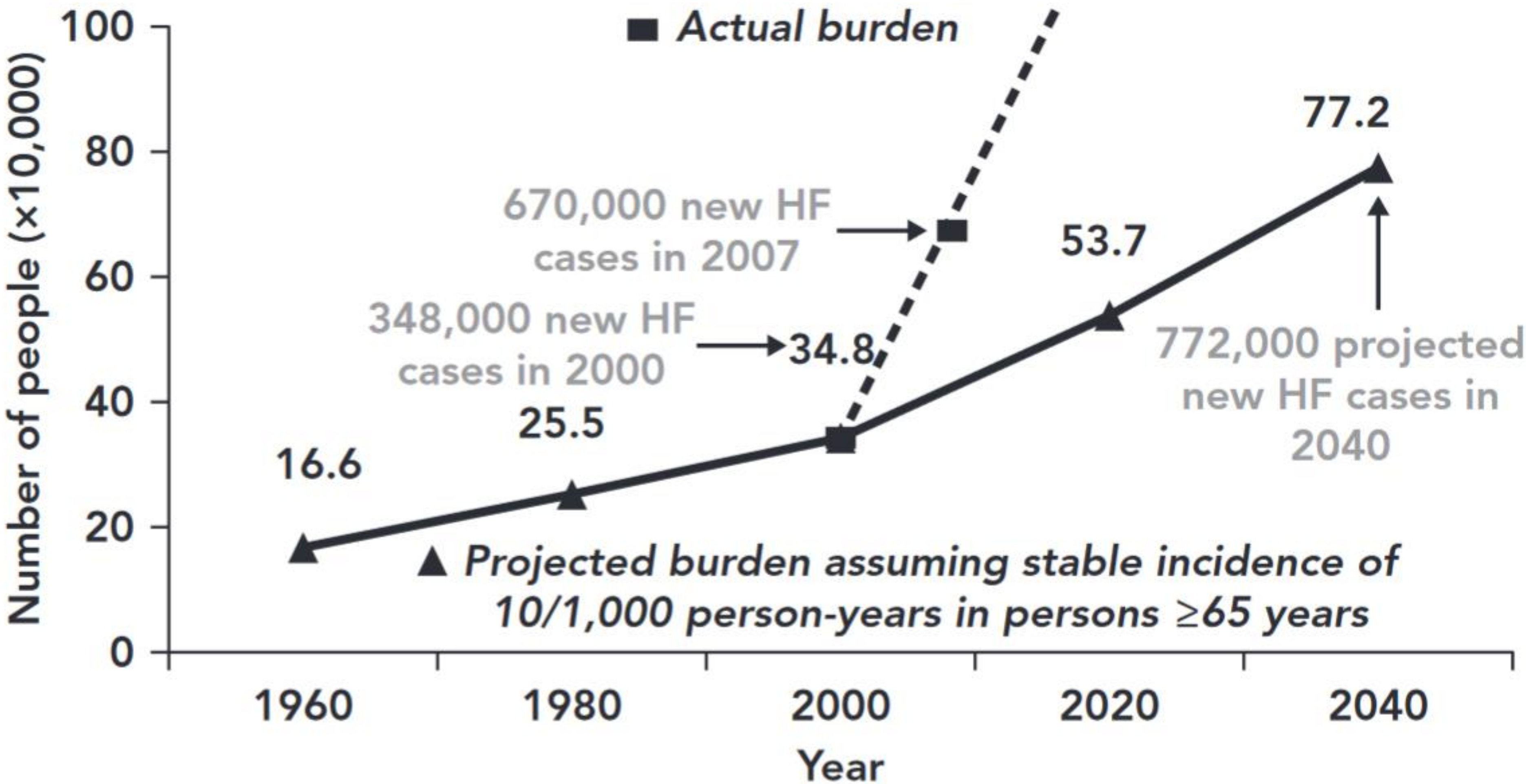
Điều trị suy tim giai đoạn cuối bằng thiết bị hỗ trợ thất

GS. BS. Đỗ Doãn Lợi

Bộ môn Tim mạch - ĐHYHN

Phó chủ tịch Hội Tim mạch Việt nam

Heart failure burden



The actual annual incidence of heart failure (HF) reported in the US (squares and dotted line) exceeded the projected annual incidence (triangles and solid line) calculated based on a stable incidence of 10 per 1,000 person-years in persons aged ≥65 years. Source: Lam et al., 2011.[69] Reproduced with permission, © 2011 John Wiley & Sons.

Tần suất Suy tim

+ Germany (2006) 1.6 % in women and 1.8 % in men
+ Sweden (2010) 1.8 % similar in men and women,
+ Italy 1.44 %

+ Important health problem in Asia, and its
+ China there are 4.2 million 1.3 %
+ Japan around 1 million 1 % of the population

+ Southeast Asia 9 million people have HF
  - 6.7 % in Malaysia
  - 4.5 % in Singapore
  - Vietnam ?

Tần suất Suy tim

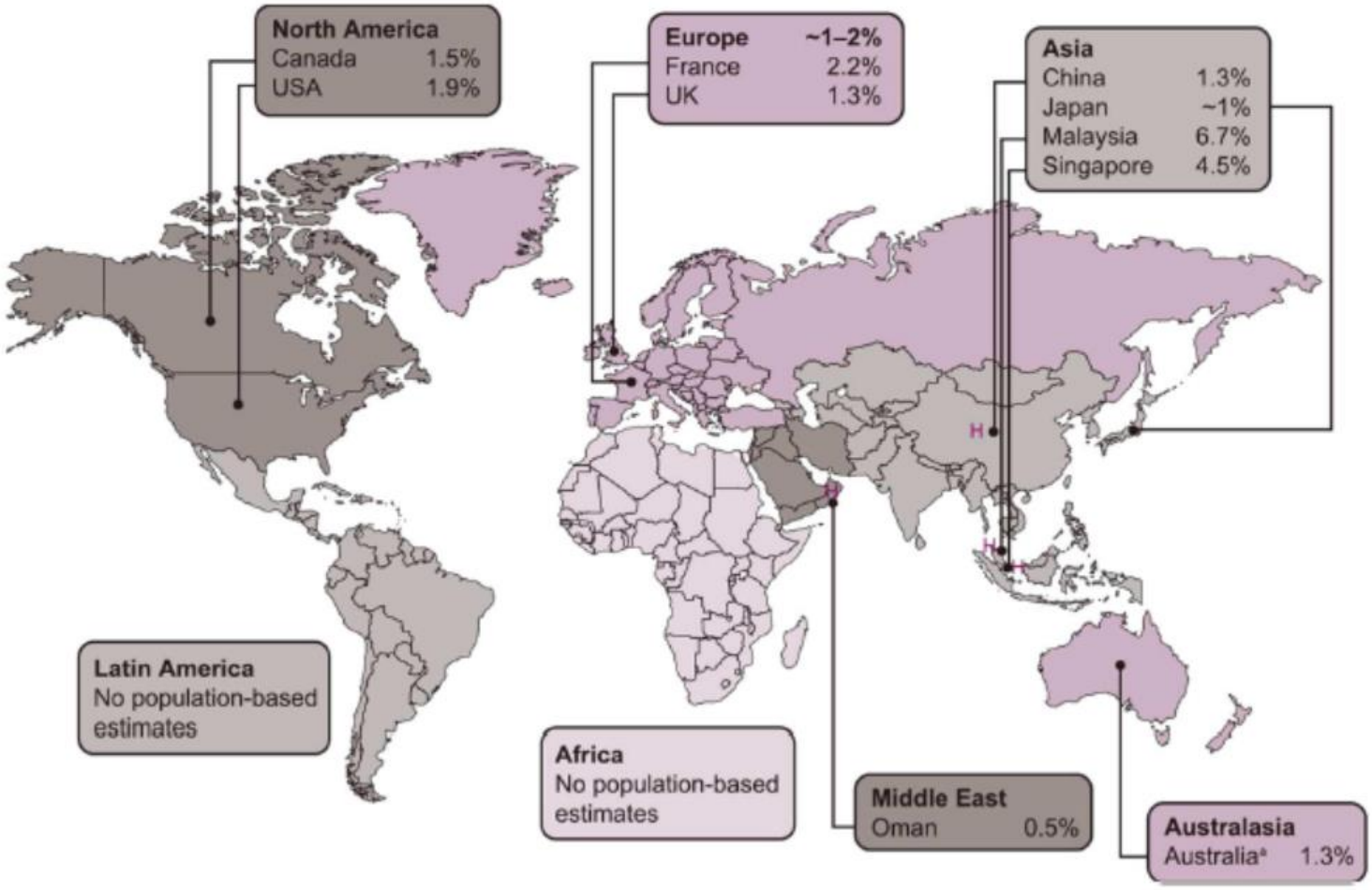
Table 1. Prevalence of Stage A HF cardiovascular risk factors in Southeast Asian nations compared with the United Kingdom and United States of America (from the World Health Organization Global Status Report 2014)

Country	World Bank Income Group Classification	Prevalence in population aged 18+ years (crude adjusted estimates with 95% Confidence Interval)				
		insufficient physical activity	Current tobacco smoking[a]	Overweight[b]	Raised blood glucose[c]	Raised blood pressure[d]
Brunei	High	—	15.8 (6.7–26.6)	47.8 (40.7–54.3)	11.2 (5.1–17.1)	19.3 (12.4–26.3)
Cambodia	Low	9.7 (8.7–10.8)	21.3 (16.0–27.5)	16.4 (12.7–20.2)	6.8 (3.6–10.3)	24.4 (17.8–30.9)
Indonesia	Lower middle	22.8 (18.0–28.1)	36.5 (29.9–45.3)	24.4 (19.9–28.9)	8.0 (4.0–11.8)	23.3 (17.7–29.1)
Laos	Lower middle	9.0 (7.4–10.8)	—	16.6 (13.1–20.6)	6.4 (3.4–9.4)	24.1 (18.3–30.4)
Malaysia	Upper middle	51.6 (46.3–56.8)	23.6 (17.2–30.7)	37.3 (31.9–42.6)	9.9 (5.5–14.2)	22.1 (16.4–27.8)
Myanmar	Low	9.0 (7.4–10.9)	22.6 (15.6–29.7)	17.4 (13.4–21.2)	6.3 (2.8–9.5)	23.7 (17.7–30.4)
Philippines	Lower middle	14.4 (3.3–42.2)	27.0 (21.5–32.3)	22.3 (18.1–26.6)	6.0 (2.7–9.2)	22.1 (16.2–28.2)
Singapore	High	33.7 (31.3–36.1)	15.6 (12.6-19.6)	34.6 (30.1–38.9)	9.8 (6.1–13.9)	14.1 (10.0–17.9)
Thailand	Upper middle	14.6 (13.4–16)	—	31.6 (26.7–36.7)	10.9 (6.3–15.5)	21.3 (15.8–26.9)
Vietnam	Lower middle	23.6 (16.2–32.5)	24.3 (19.8–29.5)	20.4 (16.2-24.6)	6.0 (3.1–8.9)	22.2 (16.3–28.3)
United Kingdom	High	40.0 (38.6–41.4)	19.9 (16.2–23.5)	66.7 (63.4–70.3)	10.1 (6.9–13.7)	15.2 (11.9–18.6)
United States of America	High	35.0 (32.5–37.6)	18.0 (14.9–21.1)	69.6 (66.0–73.5)	10.5 (6.6–13.9)	13.4 (10–17.1)

[a]In the population aged 15+ years.
[b]Body mass index ≥25 kg/m^2.
[c]Fasting glucose ≥7.0 mmol/L or on medications for raised blood glucose or with history of diabetes.
[d]Systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg.

Carolyn S.P. LamESC Heart Failure 2015;2:46–49

Figure 1 Proportion of the population living with heart failure in individual countries across the globe. H: Estimates based on a single centre. Reproduced from Ponikowski et al.[2] under the terms of its CC-BY-NC-ND license.



Carolyn S.P. LamESC Heart Failure 2015;2:46–49

Tử vong do suy tim

+ 50% HF patients life expectancy < 5 **years**

+ Advanced forms HF: 90% die within **1 year**

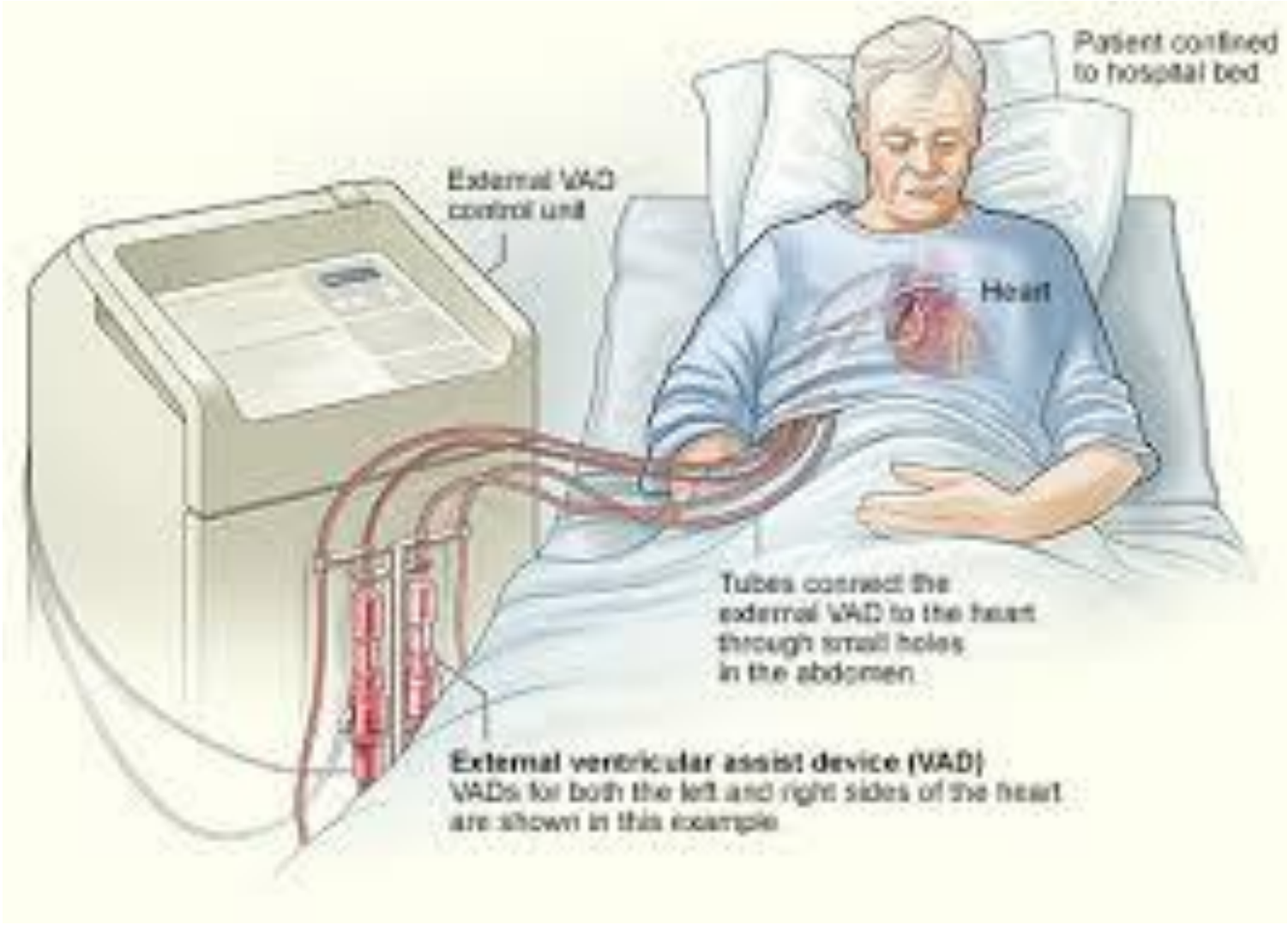
Tần suất ghép tim

- **3,500 heart transplants** / year in the world
  85 - 90 % are living one year after surgery
  75% after 3 years

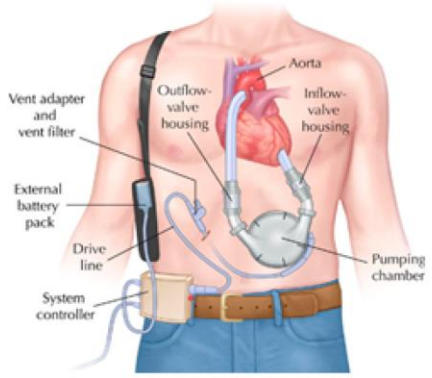
- Pediatric donor heart: ~500/year worldwide
  Nhu cầu lớn:
  Sửa tim bẩm sinh phức tạp = > suy tim với thời gian

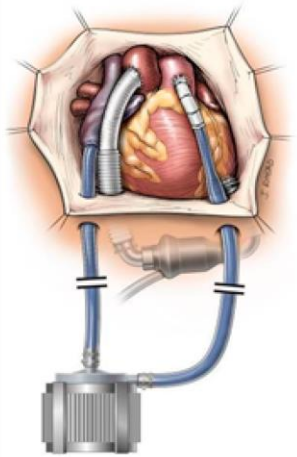
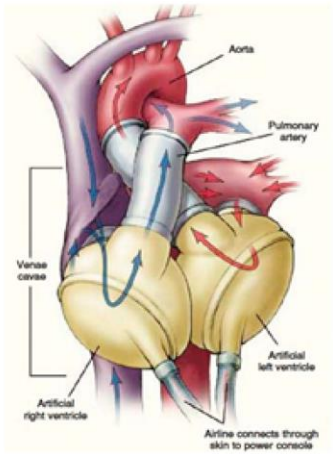
- Việt nam:
  10 năm: 30 ca

Giải pháp thay thế



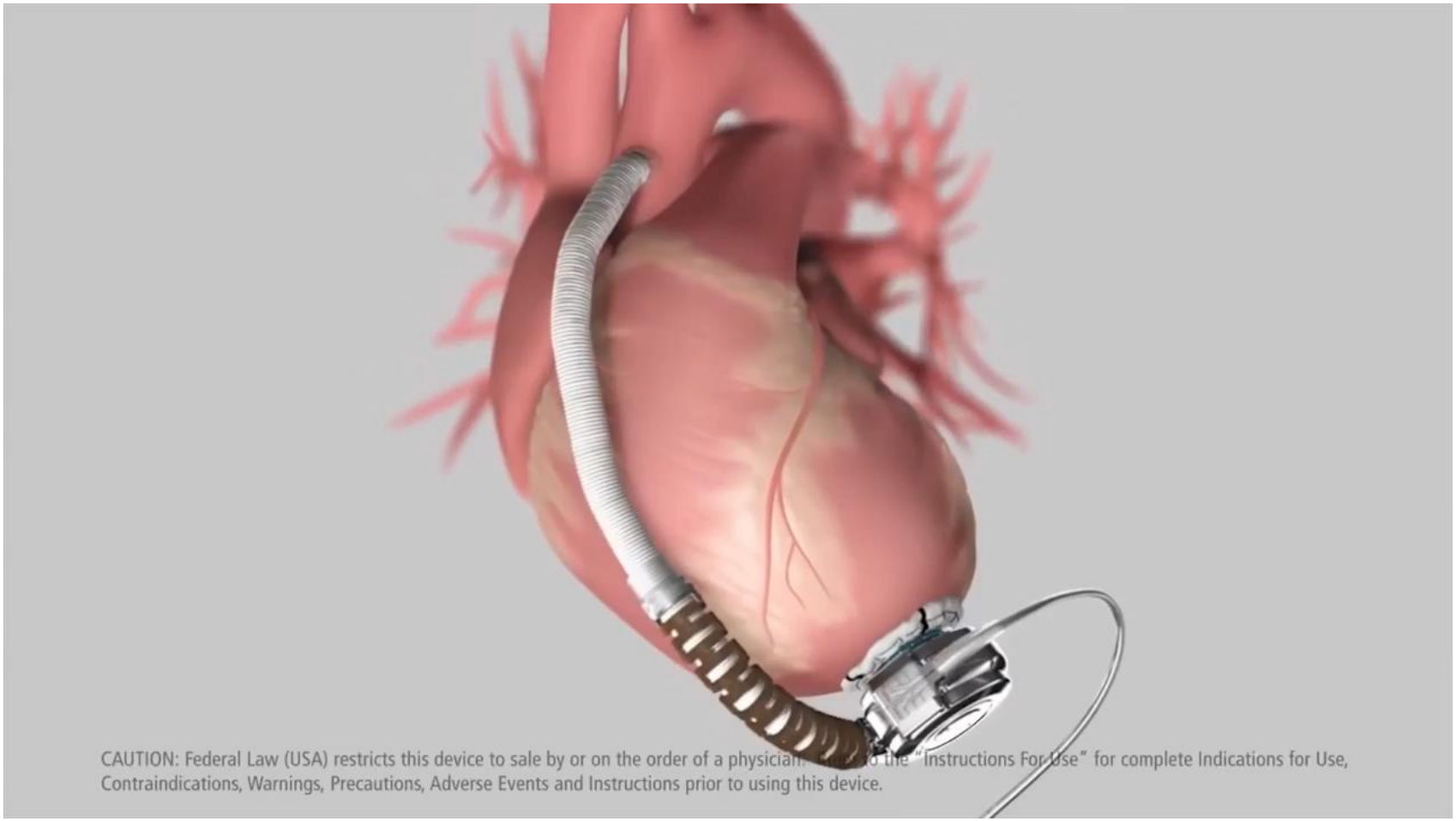
Giải pháp thay thế

<table>
<tr><th colspan="4">First Generation</th></tr>
<tr><th>LVAD</th><th>RVAD</th><th>BiVAD</th><th>TAH</th></tr>
<tr>
<td> 

HeartMate XVE LVAS</td>
<td> 
CentriMag RVAD</td>
<td> 
Berlin Heart EXCOR</td>
<td> 

Jarvik 7</td>
</tr>
<tr><th colspan="2">Second Generation</th><th colspan="2">Third Generation</th></tr>
<tr>
<td colspan="2"> 
HeartMate II</td>
<td colspan="2"> 
HeartMate III</td>
</tr>
</table>

HeartWare



Mục đích VAD

- Indications for implanting an LVAD:

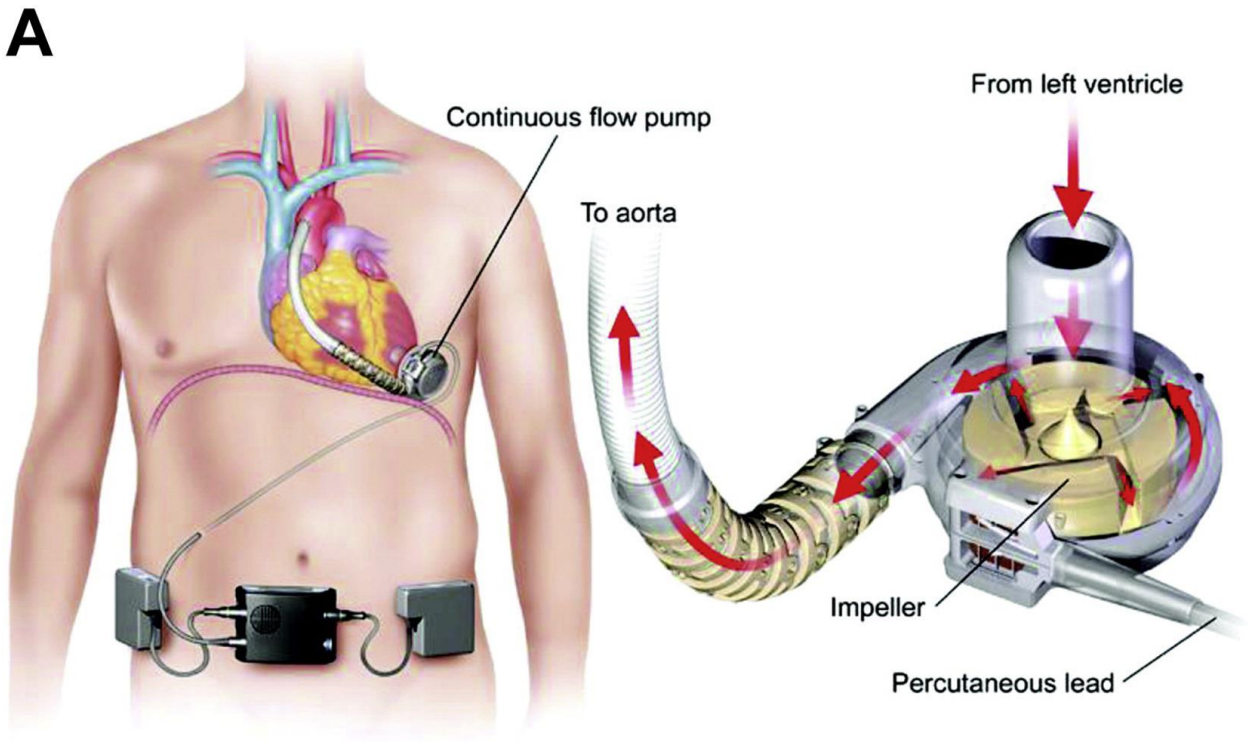
  - **Điều trị bắc cầu trước ghép**
    - The patient must meet criteria to be listed for a heart transplant
    - The VAD is taken out at time of transplant

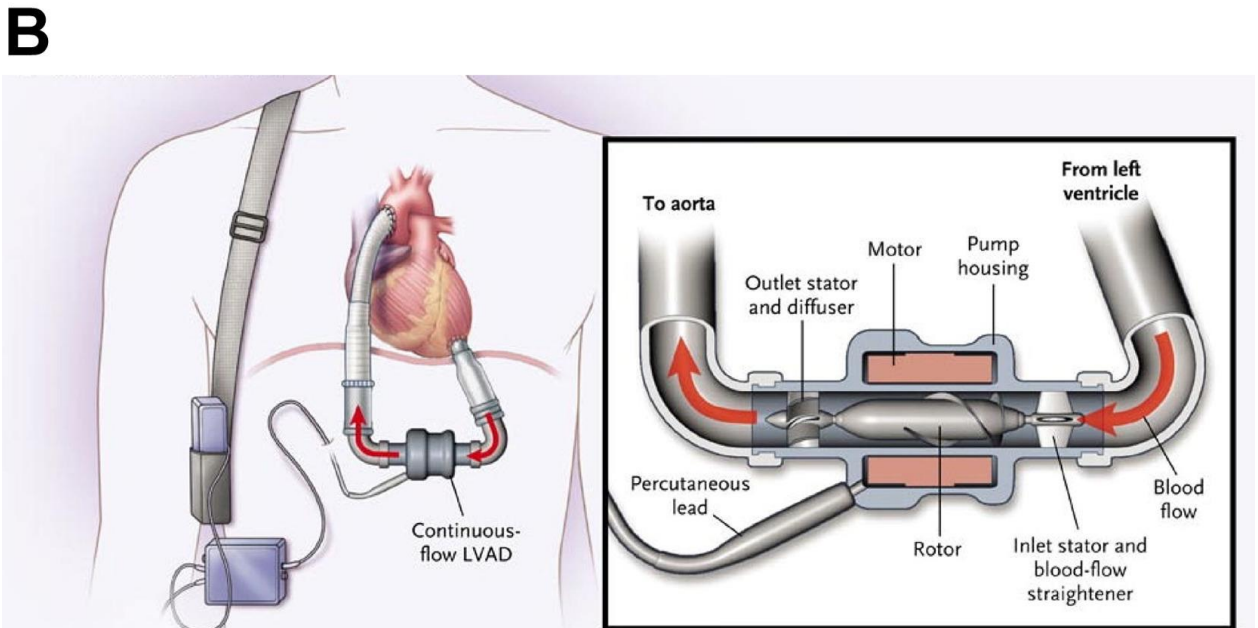
  - **Điều trị đích**
    - The patient does not qualify for a heart transplant but meets criteria for Destination Therapy
    - The patient lives the rest of their life with an VAD

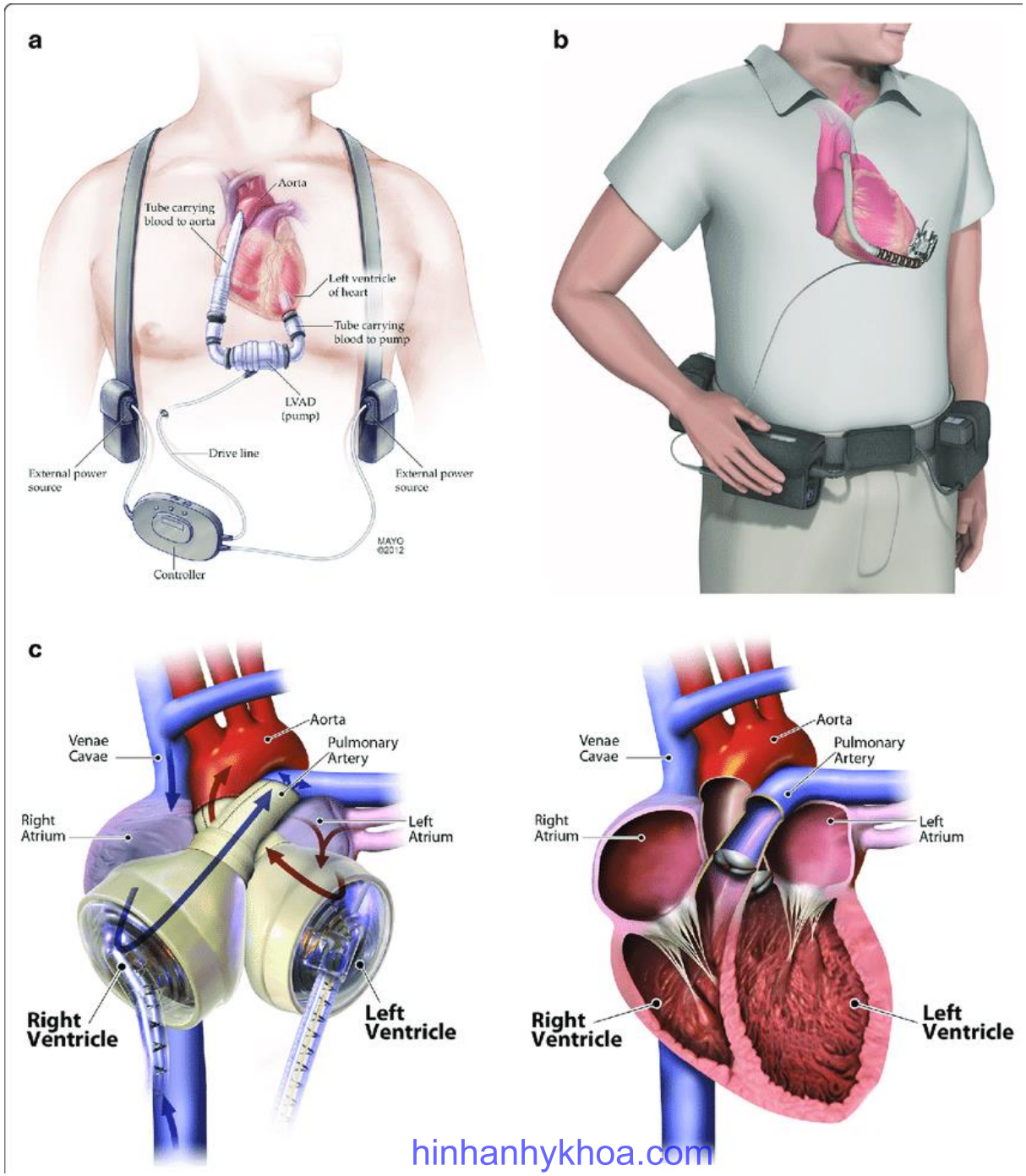
  - **Bắc cầu chờ hồi phục**
    - VAD for a few days or weeks, provides temporary support
    - Ex. Patient with post partum cardiomyopathy

Chỉ định – Chống chỉ định

Indications	Contraindications					
New York Heart Association Class IV congestive heart failure refractory to maximal medical therapy and conventional surgery	Limited life expectancy	Age >80 y	Active malignancy			
Ejection fraction <25%	Severe comorbidities precluding meaningful outcome	End-stage renal disease (glomerular filtration rate < 30 or creatinine clearance < 30)	Severe liver disease (bilirubin < 2.5 or international normalized ratio > 2.0 with cirrhosis or portal hypertension)	Severe lung disease (obstructive or restrictive, home O2); pulmonary infarction within the past 6 wk	Severe vascular disease; severe arthritis	Unconfirmed neurological status, unresolved stroke, or severe neuromuscular disorder
Reduced functional capacity as measured by a maximal oxygen consumption VO2 <14 mg/kg/min	Hematologic	Active severe bleeding; chronic thrombocytopenia	Active infection	Refusal of blood transfusions	Confirmed heparin induced thrombocytopenia	Intolerance to anticoagulation
Exceptions for select patients may include clinical trial protocol requirements	Anatomic	Congenital heart disease	Hypertrophic cardiomyopathy	Large ventricular septal defect	Body mass index precluding implantation or rehabilitation	
	Hemodynamic	Severe independent right heart failure	Pulmonary vascular resistance >6 or transpulmonary gradient >15 on testing with inhaled nitric oxide, flolan, or intravenous nitroprusside	Existing significant aortic insufficiency unable to be corrected		
	Psychosocial	Evidence of ongoing alcohol, smoking or drug use or dependency	Inability to provide informed consent	Inability to adhere to medical regimen	Inability to maintain device (drive line, console)	Active mental illness or psychosocial instability


A
Continuous flow pump
From left ventricle
To aorta
Impeller
Percutaneous lead


B
Continuous-flow LVAD
To aorta
From left ventricle
Motor
Pump housing
Outlet stator and diffuser
Percutaneous lead
Rotor
Inlet stator and blood-flow straightener
Blood flow



Survival after LVAD

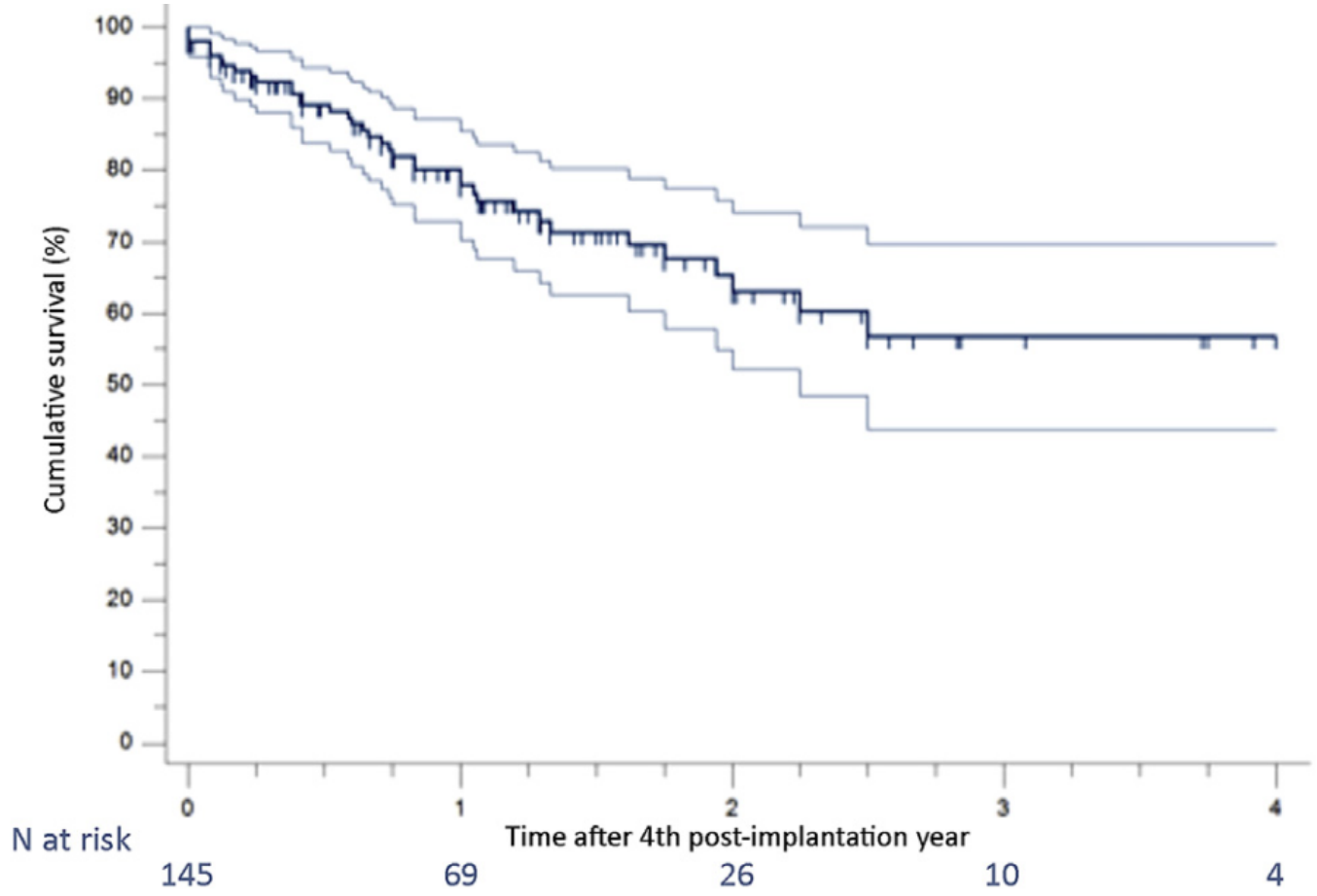


Fig 1. Survival among patients with left ventricular assist devices who survived 4 years or longer.

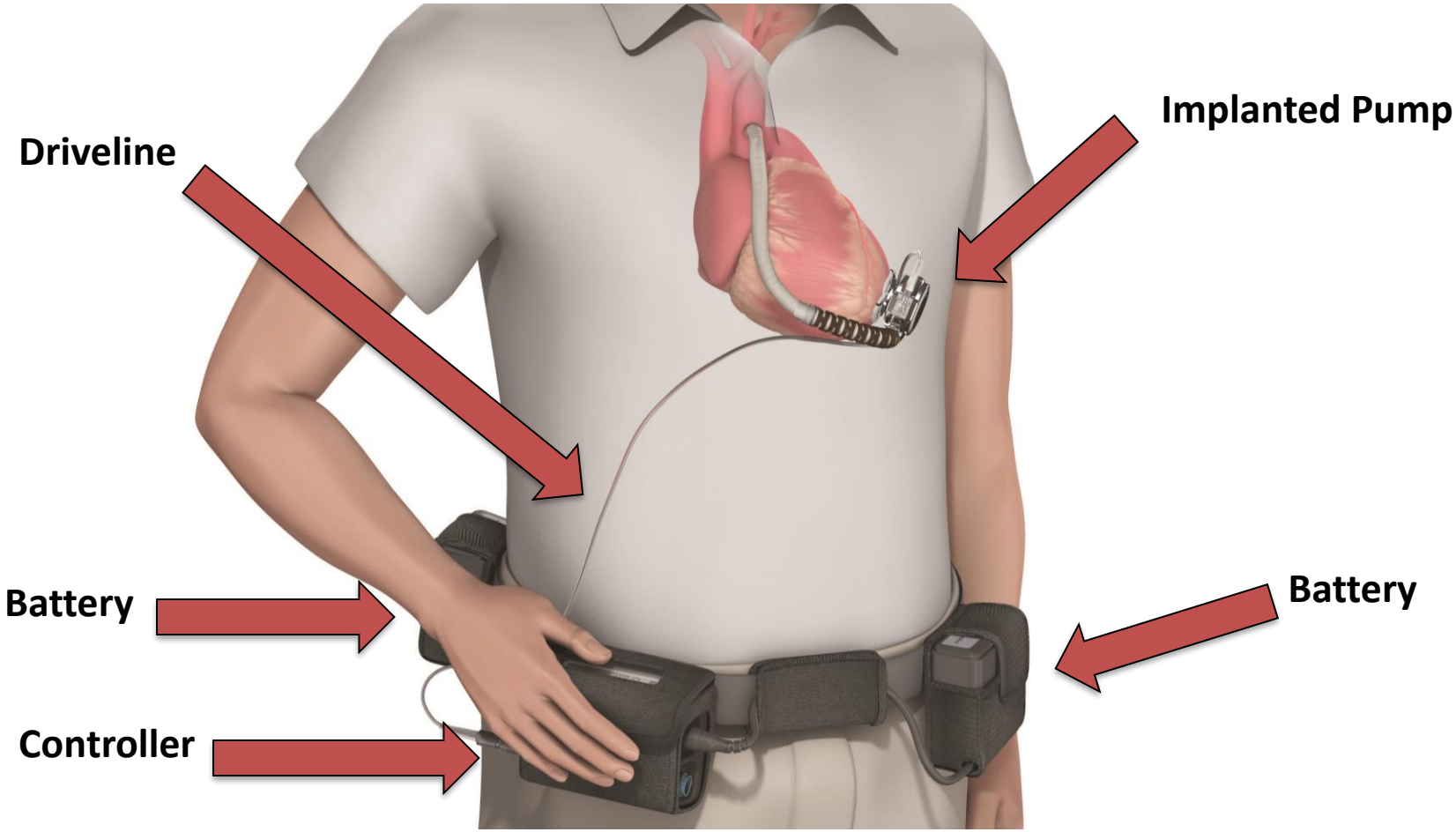
Igor Gosev Ann Thorac Surg 2018;105:696–701

Các loại máy chính

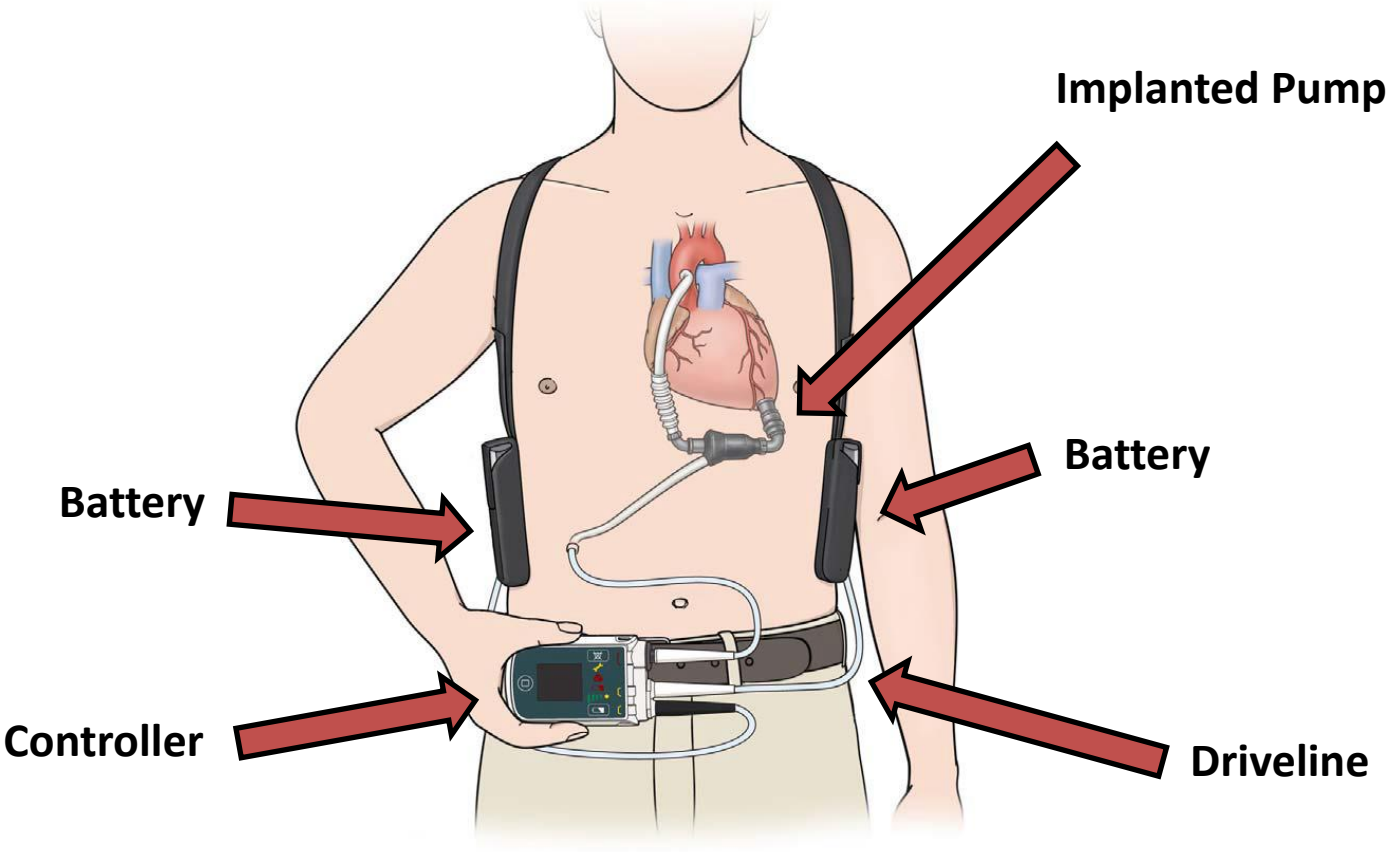
Table 1. Device Types Currently Approved by the US Food and Drug Administration and Their Mechanical Properties

Device Type	HeartWare HVAD System	HeartMate II	HeartMate III
Speed range, rotations per minute	2400–3200	6000–15,000	3000–9000
Rotor design	Centrifugal	Axial	Centrifugal
Pump position	Intrapericardial	Pump pocket	Intrapericardial
Blood flow gaps, mm	≈0.05	≈0.08	≈0.12
Food and Drug Administration–approved indication	Bridge to transplant (2012) Destination therapy (2017)	Bridge to transplant (2008) Destination therapy (2010)	Bridge to transplant (2017) Destination therapy (2017)
Magnetic levitation	*		*
Artificial pulsatility			*
High inlet suction		*	

HeartWare System

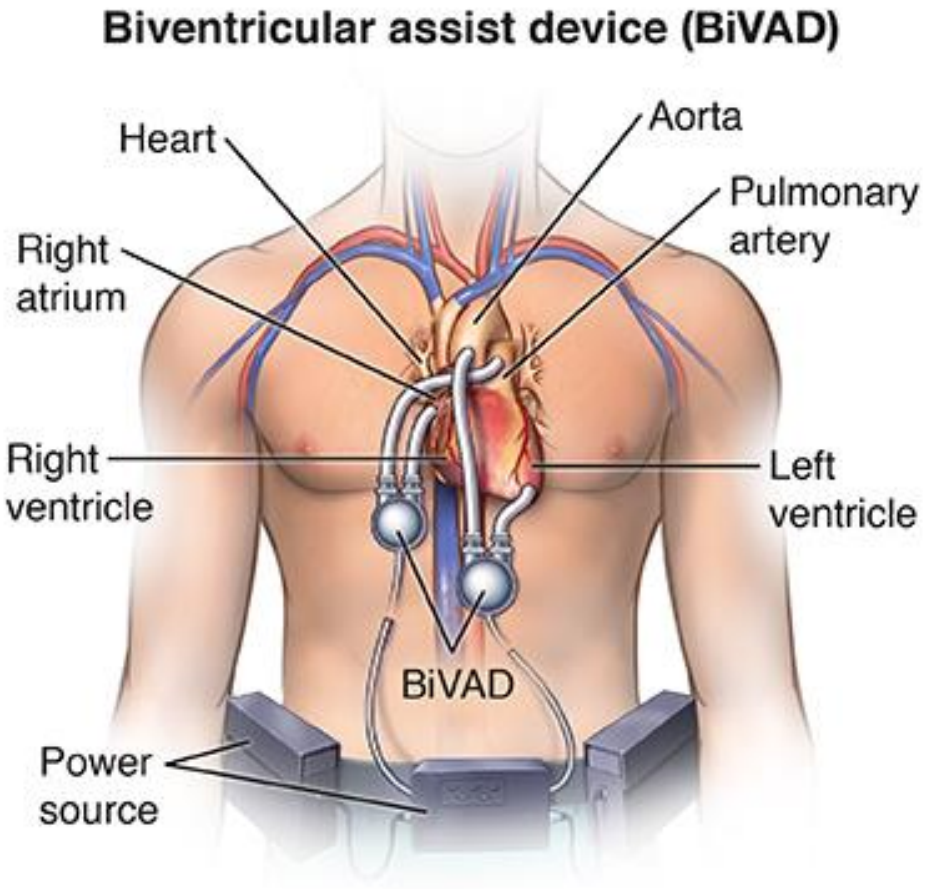


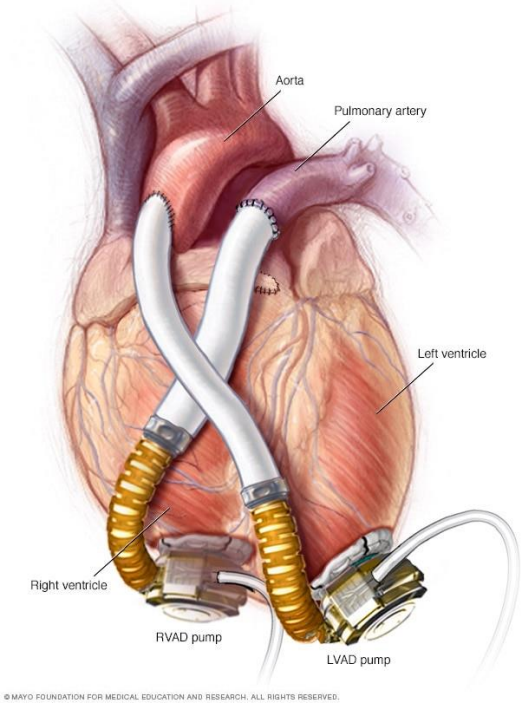
HeartMate II System



Abbott-Thoratec HeartMate 3

BiVAD





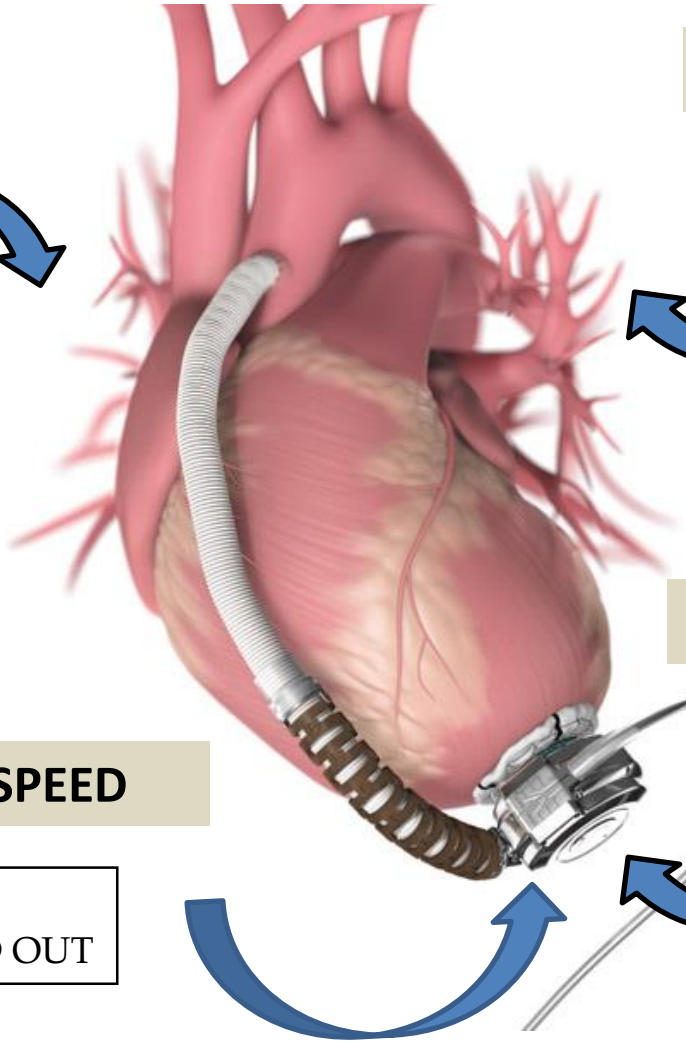
LVAD Patient Management

PRELOAD

Volume
Blood Pressure
CVP / PVR
Right Heart Function
Valvular Function
Rhythm

AFTERLOAD

SVR
MAP 65-85



ANTICOAGULATION

Coumadin
ASA
INR 2-3

PUMP SPEED

Set RPM to
BLOOD IN = BLOOD OUT

Biến chứng có thể gặp

Table 4. Various Adverse Events, Their Incidence, Timeline, Mechanism, and Proposed Therapies

Adverse Event	Incidence Range, %	Timeline	Risk Factors	Diagnostic Modality	Treatment
Right heart failure	15 to 25	Bimodal (acute or delayed onset)	Pulmonary hypertension, existing right ventricular dysfunction	Clinical; echocardiography	Inotropy; right ventricular assist device
Pump thrombosis	1.1 to 12.2	Varied	Inadequate anticoagulation; mechanical; low-flow	Hemolysis; echocardiography; intraoperative	Thrombolytics; device exchange
Gastrointestinal bleeding	15 to 30	Varied; recurrent	Low pulsatility; acquired von Willebrand factor deficiency; arteriovenous malformation; anticoagulation	Endoscopy	Proton pump inhibitor; cauterization
Driveline infection	15 to 24	Varied	Driveline; poor hygiene; hematoma;	Clinical; visual inspection	Antibiotic therapy; device exchange if systemic
Stroke	13 to 30	Varied; possible hemorrhagic conversion	Hypertension; anticoagulation;	Computed tomography scan or magnetic resonance imaging	Multifactorial
Aortic insufficiency (moderate or severe)	30% at 2 yr	Chronic	Chronic nonopening of aortic valve	Echocardiography	Surgical or transcatheter valve repair or closure

Mayo 24 HR **VAD HOTLINE**

Mayo VAD Coordinator: 480-342-2999

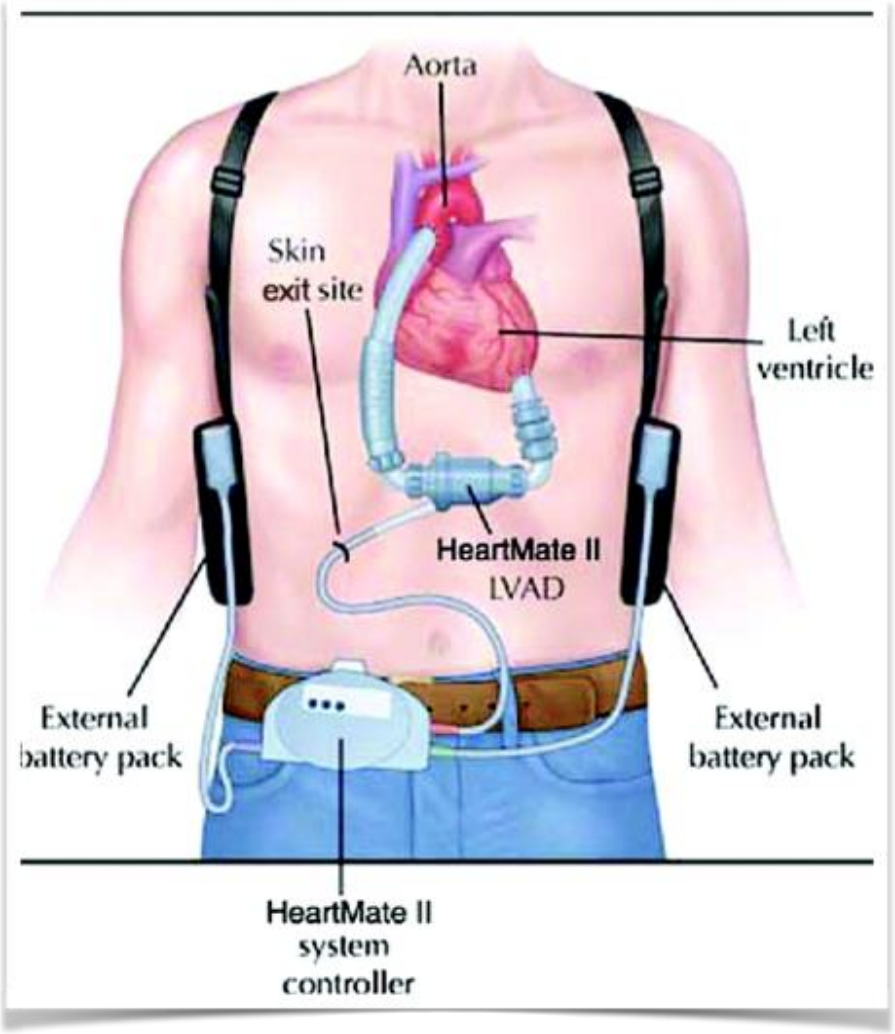
- The **VAD Hotline** will connect you to a VAD Coordinator in under 2 minutes
- **The 24 Hr VAD Hotline** is for patients, caregivers, and first responders to use as a consult service for emergent and non-emergent needs.
- With calls involving 911, patients and caregivers are instructed to give first responders the phone when you arrive so EMS is immediately in communication with a VAD expert that is familiar with details about the patient
- If 911 call comes from a bystander, an identifying sticker will be on the Controller with basic patient information and VAD Hotline number.

VAD Special Considerations

- **VAD patients are unique and require specialized care**
  - Routine assessments such as blood pressure, pulses, and pulse-oximetry may not be unattainable
  - Chest compressions are usually not indicated
  - The patients carry external equipment: a controller and power sources that operate the implanted pump though a single driveline

VAD Patient Assessment

- Attempt to auscultate over the apex of the heart for a “whirling” or “smooth, humming” sound indicating that the VAD is working
- A cable exits the abdominal wall that connects the device to power and the control unit
- Many VAD patients also have an implanted cardiac defibrillator



VAD Patient Assessment

- **Blood Pressure (BP)**
  - **BP** taken with a manual cuff
  - **Automatic BP readings are considered unreliable**

- **Pulse**
  - A palpable pulse is variable and **clinically insignificant** in VAD patients

- **Pulse Oximetry**
  - **Can be unreliable**
  - Look for physical s/s of ↓ oxygenation

Patient Assessment cont.

- EKG is typically unaffected

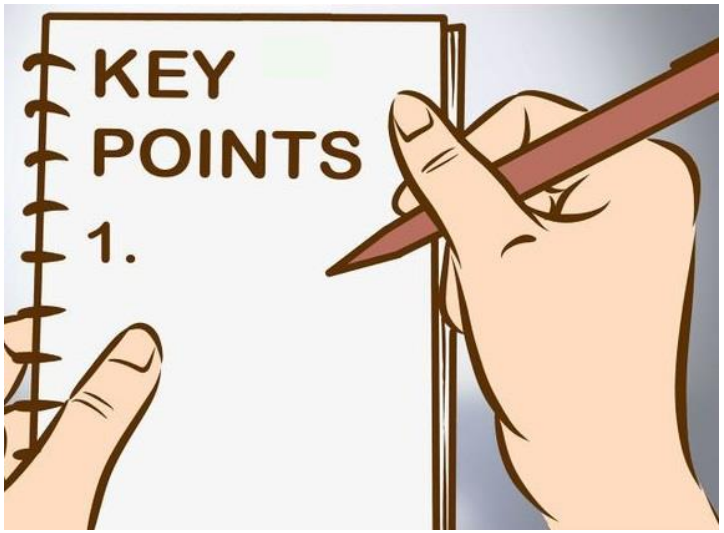
- Patients are at high risk for **bleeding complications** due to blood thinner use
  - Trauma
  - Falls
  - GI bleed

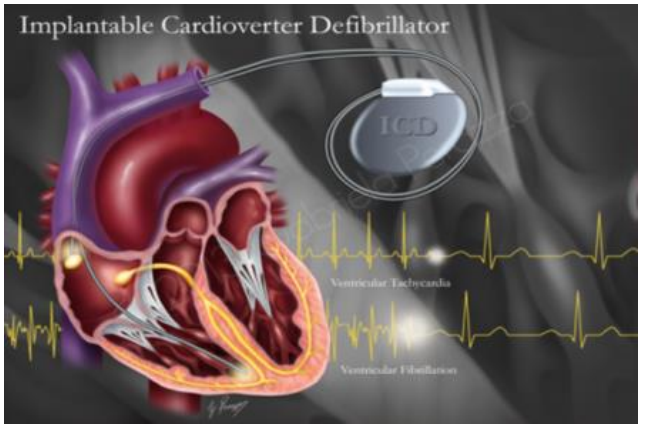
VAD Patient Rhythm Assessment

- Because they have a blood pump, VAD patients may be stable in V-Tach or V-Fib
- VAD flows may be affected
- Persistent arrhythmias are treated **after** contacting the VAD coordinator
- Many VAD patients have an ICD / Pacemaker
  - If patient's ICD delivers a shock, notify VAD Coordinator
- Okay to defibrillate & cardiovert VAD patients per ACLS protocol
- Okay to administer anti-arrhythmic medications per ACLS protocol

VAD Patients with Dysrhythmia

- #1 = **Contact VAD coordinator**
- #2 = **Treat the patient, not the monitor!**





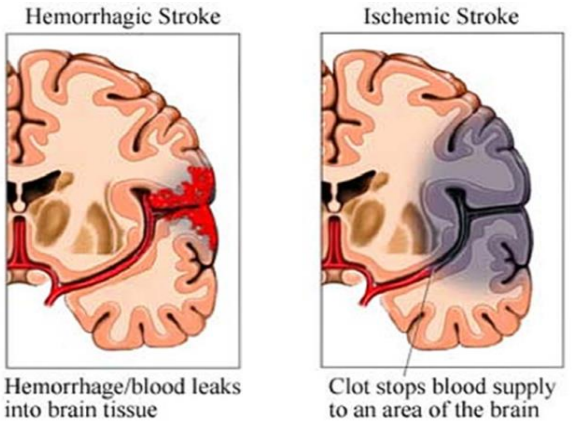
VAD Patient Neuro Assessment

- All VAD patients are on anticoagulation medications
- They are at high risk for embolic or hemorrhagic stroke.
- Level of consciousness may deteriorate rapidly
- Because patients are already anti-coagulated, they do not follow routine stroke protocol

VAD Patients & Potential Stroke

Key point:

Transport these patients to their VAD center, not the closest stroke center!



Assessing for signs of Hypovolemia

Normal Flow Range 4 – 6 L/min

Asymptomatic

Sub-optimal Flow 2.5 – 3.5 L/min

Asymptomatic → Symptomatic

May be dizzy, lightheaded, fatigued, change in LOC

Low Flow < 2.5 L/min

Asymptomatic → Symptomatic

May be dizzy, lightheaded, fatigued, change in LOC

VAD complications: infection

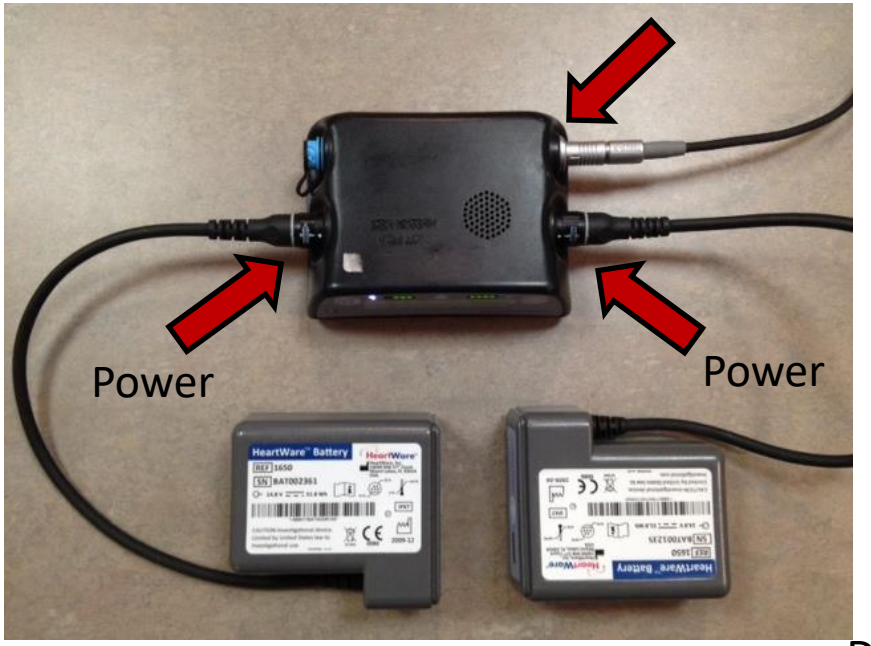
- Many hospital admissions in VAD patients are secondary to infection, not cardiac problems.
- Assess for signs of infection (especially at the insertion point) or sepsis

Critical VAD Connections

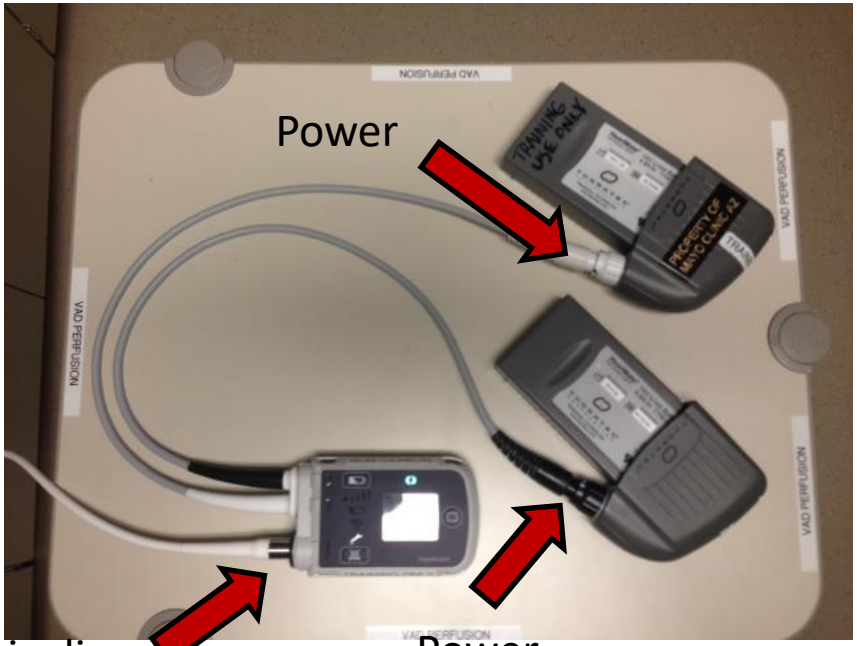
Never disconnect both power sources! Never disconnect driveline!

HeartWare HVAD

Driveline



HeartMate II



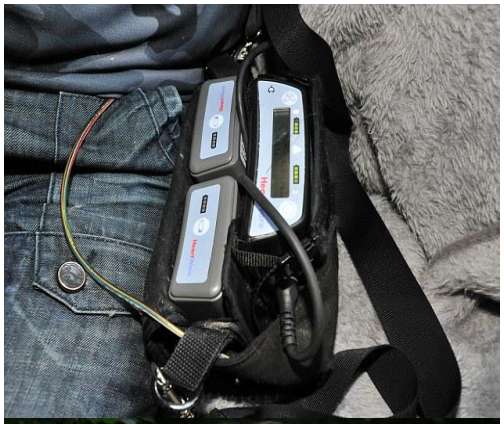
External VAD Components

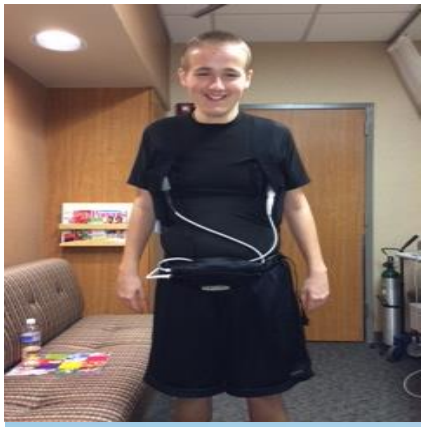
Patients have options for carrying their external equipment to best suit their comfort and lifestyle

Ensure that the equipment is protected at all times with **no stress on the driveline**

Patients will have an additional supply bag for their extra batteries and backup Controller close at hand. **This bag should always accompany the patient on transport**

External VAD Components





The Controller

Alarms have symbol and message on screen

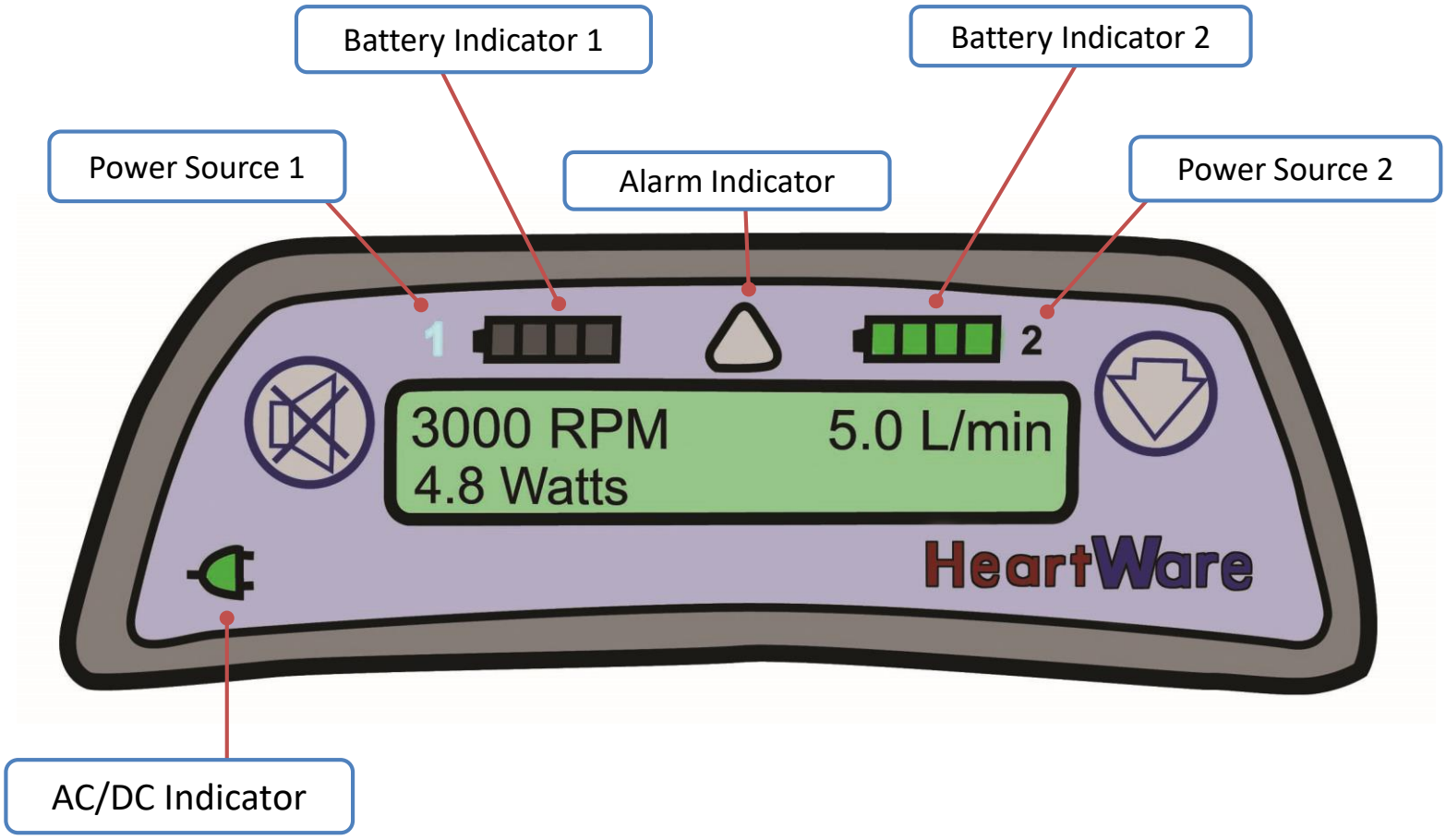
Yellow (beeps)
Pump is ON

Red (steady tone)
Pump may be OFF

For HeartMate 2 and 3 press MENU button to access parameters

ALARM SILENCE

HVAD® Controller: Display Overview



Power Management

DC Adapter

AC Adapter

HVAD® Controller

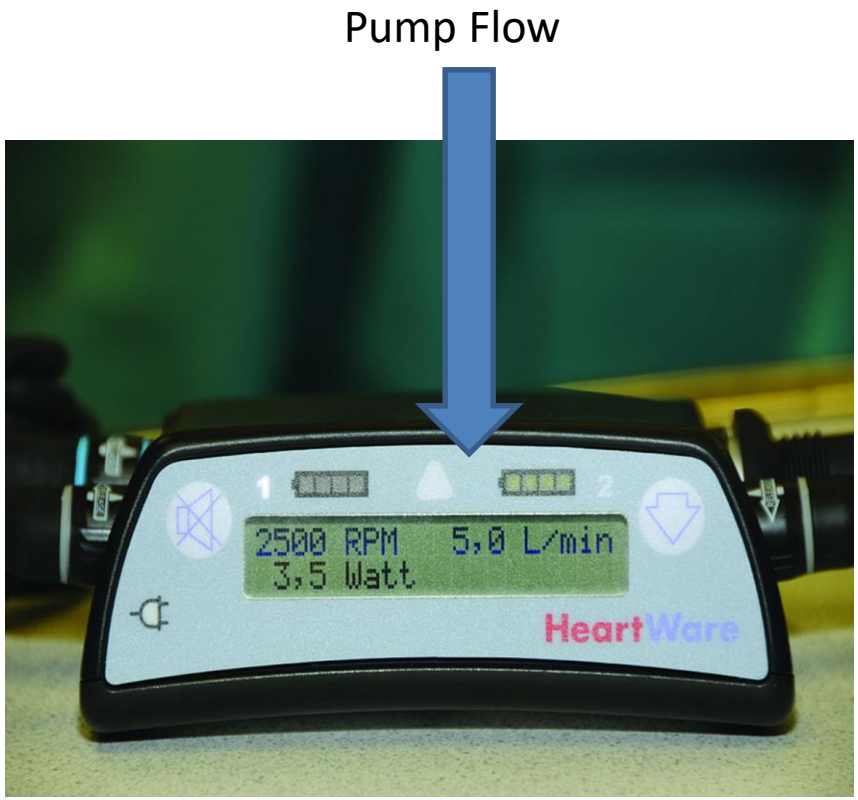
HeartWare Batteries and Charger

- Patients are responsible for managing their power
- They have 6-8 batteries in rotation and a home charger
- Batteries generally last 8 – 14 hours per pair
- Exchanged one at a time, so one power source is always connected to the Controller
- Patients only need to be on A/C power when sleeping

Assessing Pump Flow

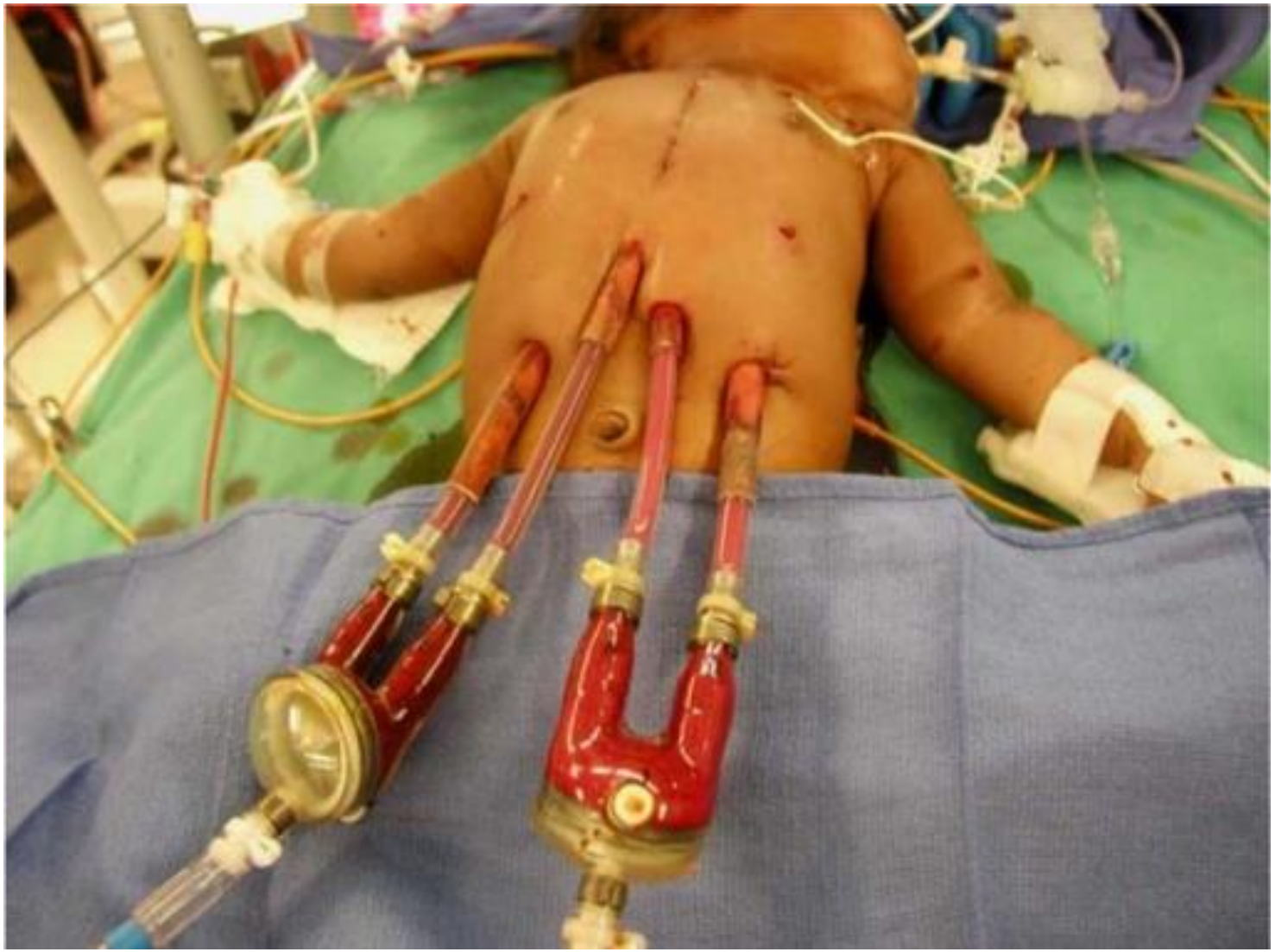
Flow (L/min)

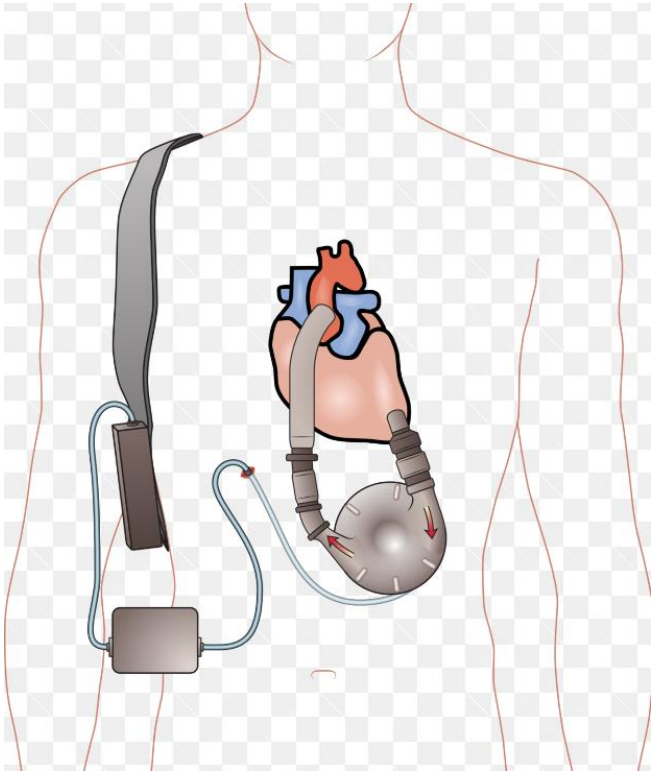
- Average adult Cardiac Output at rest is ~ 5 L/min
  - Body size / blood volume effects pump flow potential
- The Flow parameter is an estimate
- Flow will mainly fluctuate with changes in activity, body position, and blood volume
  - Hyper / hypovolemia
- Other physiologic conditions can also effect flow:
  - Right Heart Function
  - Rhythm disturbances
  - Hypo / hypertension
  - Valvular function
  - Pulmonary hypertension
  - Thrombosis

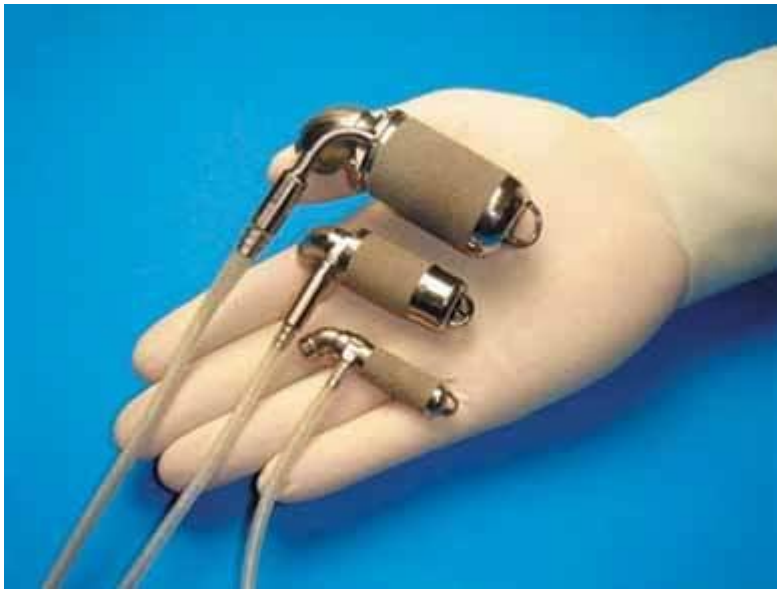


Trẻ em

- Centrifugal pump
  - + PediMag
    (St. Jude Medical, Inc.)
  - + Rotaflow
    (Maquet Cardiovascular LLC, Wayne, NJ, USA)
  - + Jarvik Infant VAD
- Pulsatile pump
  - + Berlin EXCOR

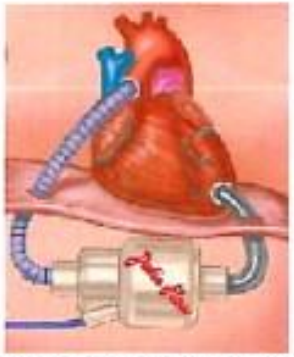




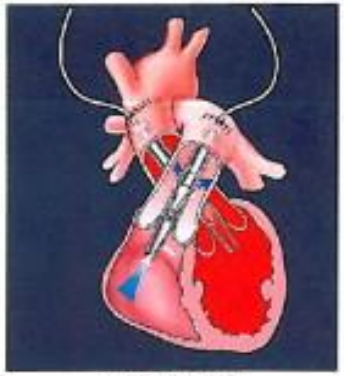


Jarvik

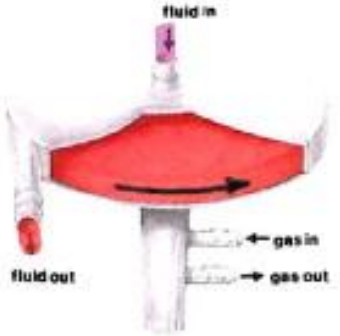
Pediatric Circulatory Support Systems



PediaFlow Ventricular
Assist Device
University of Pittsburgh
Harvey Borovetz, Ph.D.

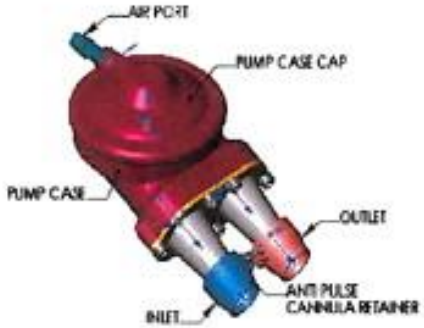


PediPump
Cleveland Clinic
Lerner College of Medicine-CWRU
Brian Duncan, M.D.

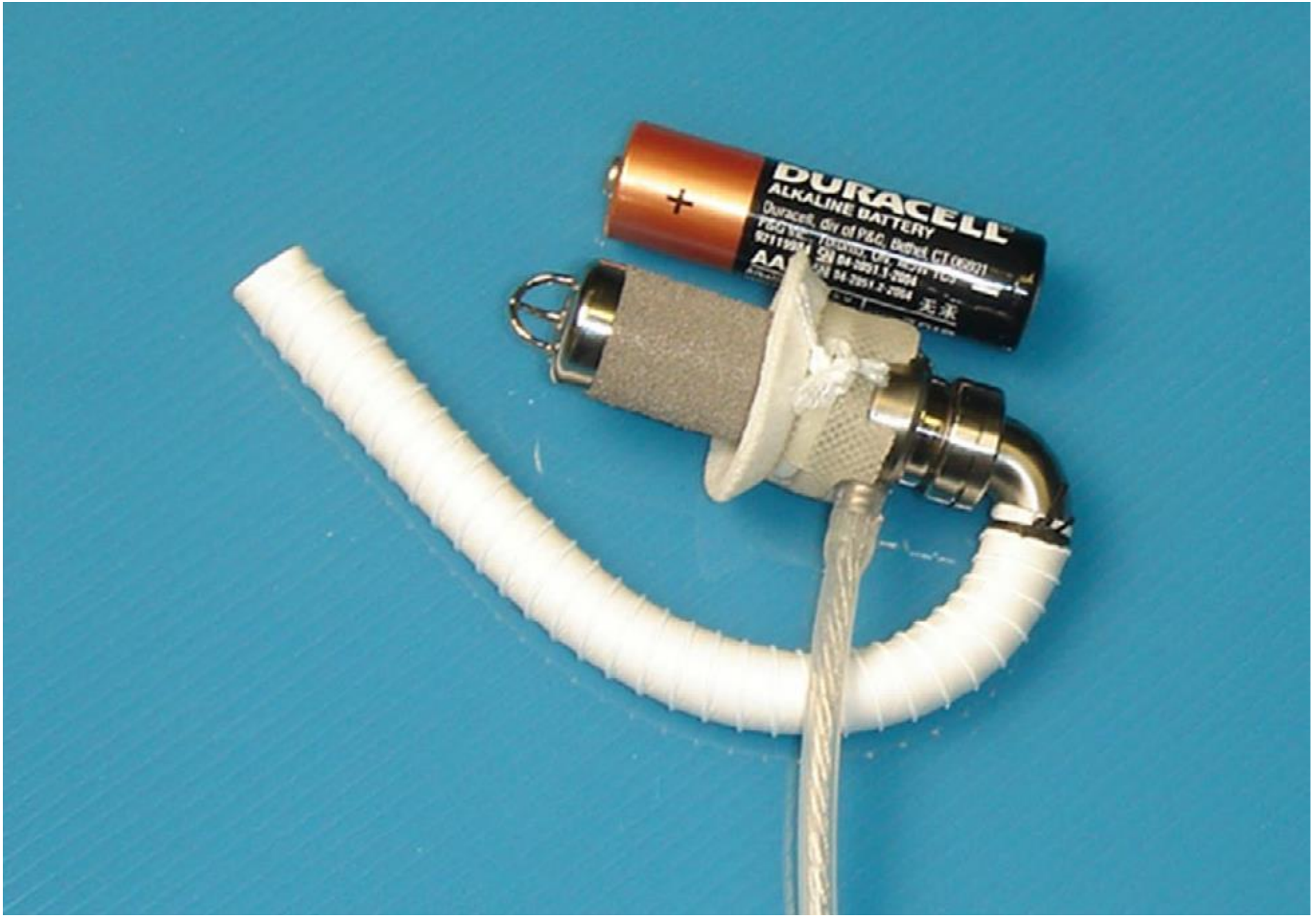


Pediatric Cardiopulmonary
Assist System
Ension, Inc.
Mark Gartner, M.S.

Child-size and Infant-size
Jarvik 2000 LVADs
Jarvik Heart, Inc.
Robert Jarvik, M.D.



Pulsatile Pediatric Ventricular
Assist Devices
Penn State University
Bill Weiss, Ph.D.


DURACELL
ALKALINE BATTERY

Định hướng – Tương lai

- Nhu cầu ngày càng tăng
- Nguồn tạng ghép ngày càng thiếu
- Công nghệ ngày càng cao
- Giá thành ngày càng giảm

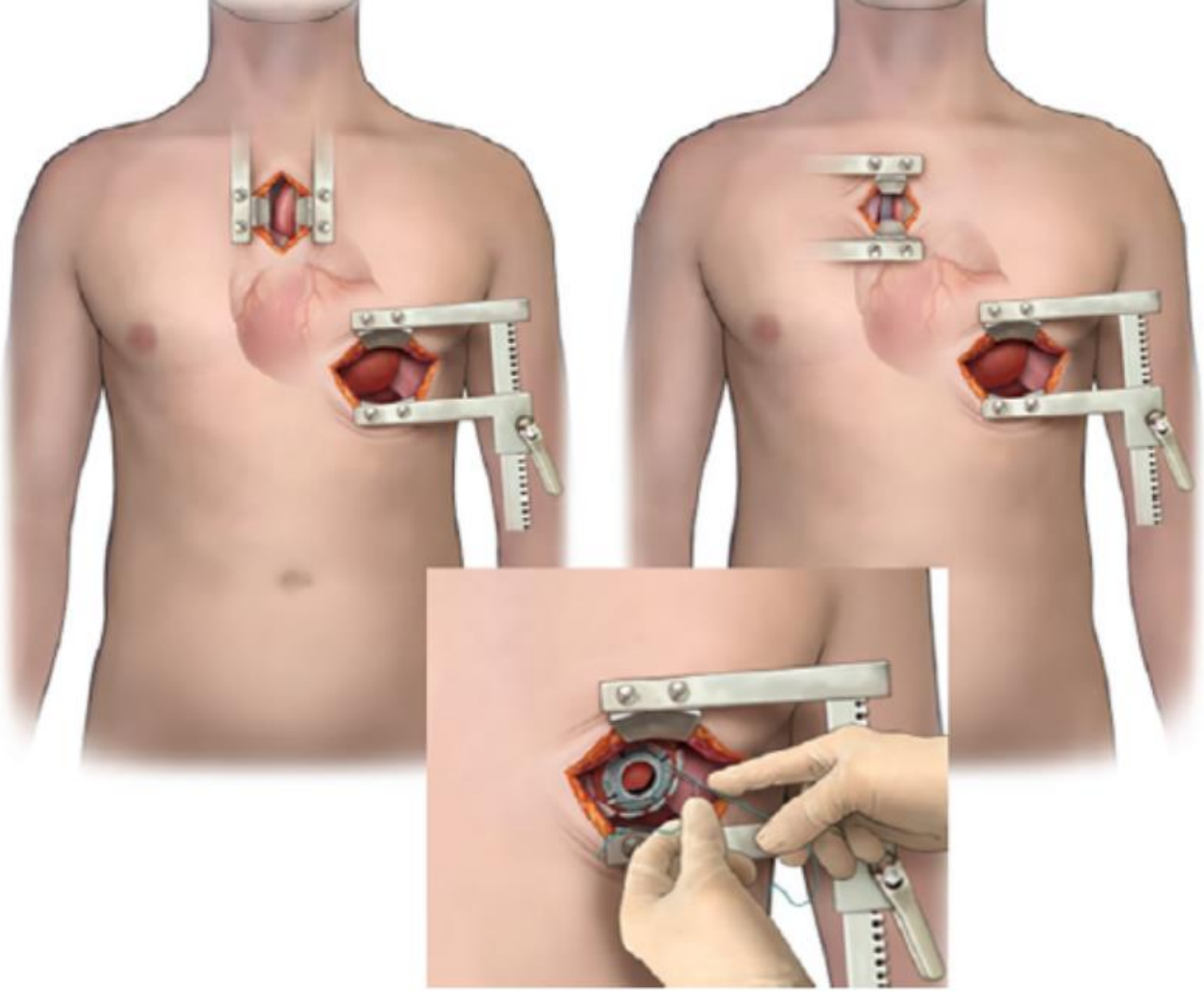
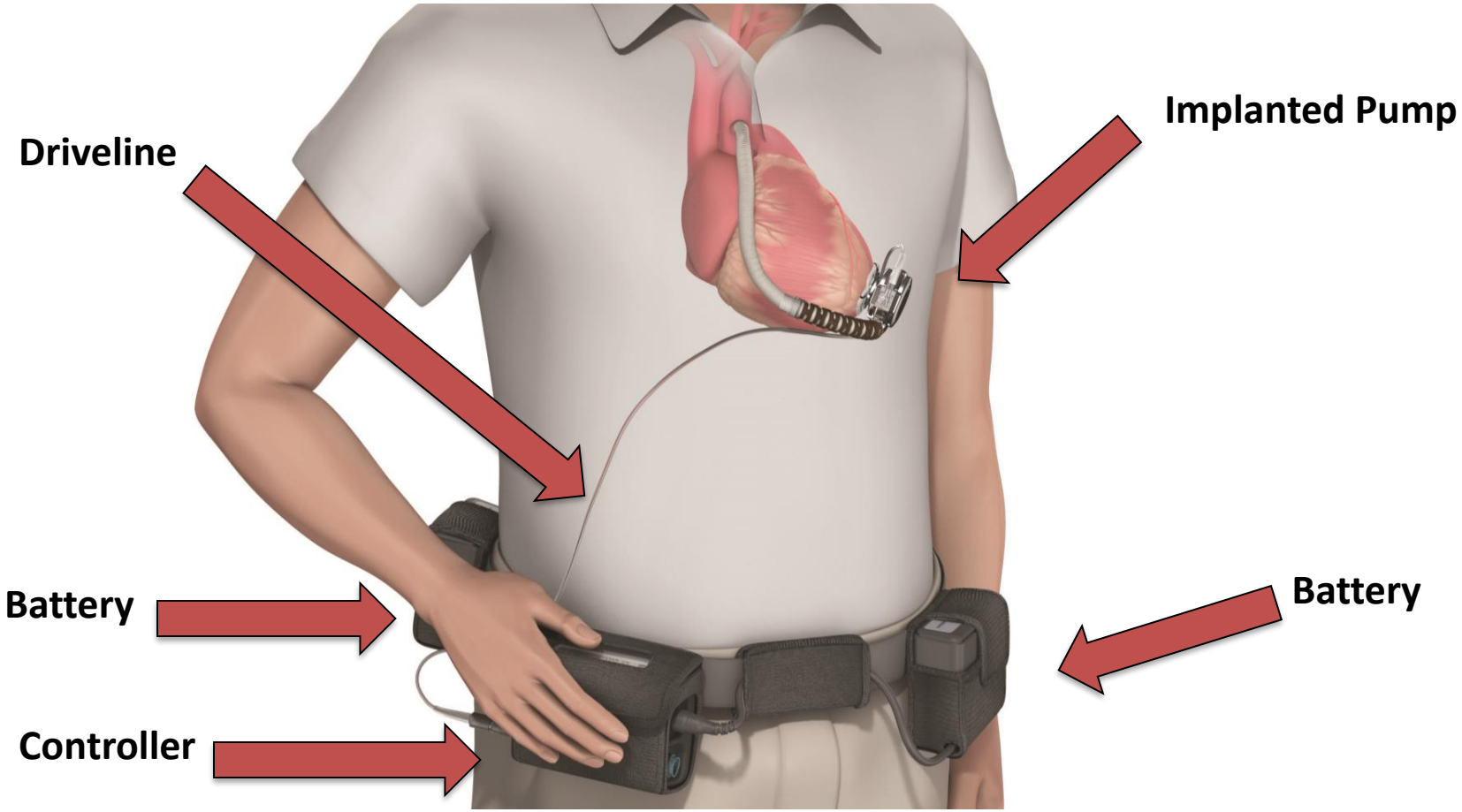


Figure 1 Implantation of the HVAD pump using a lateral thoracotomy approach.

MVAD và HVAD

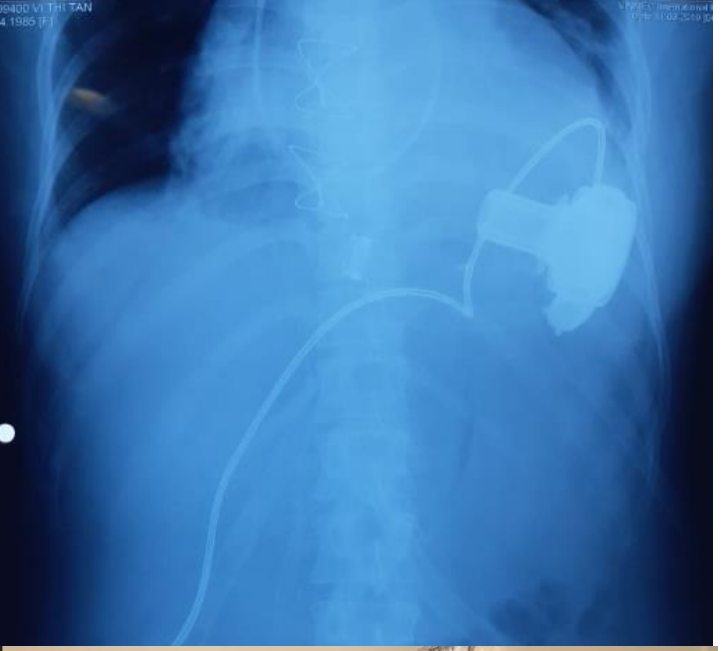
HeartWare System



Bộ điều khiển

Pin sạc không dây ?!

Không còn dây dẫn

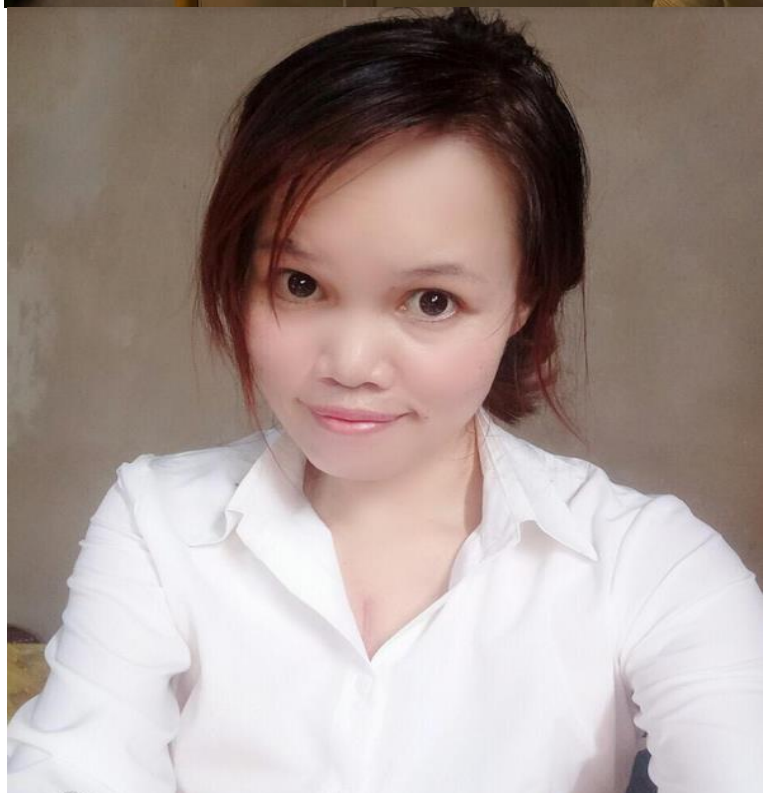


Chân

Thành

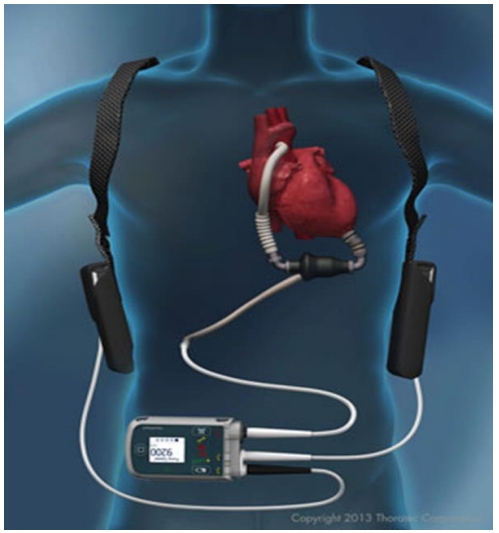
Cám

Ơn



Questions?

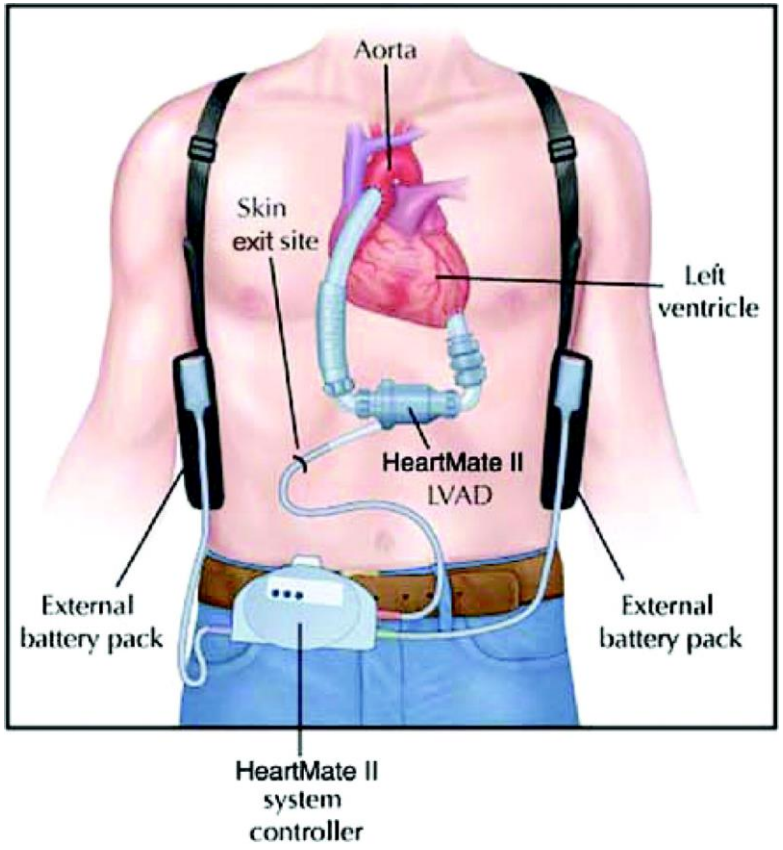
VAD Overview



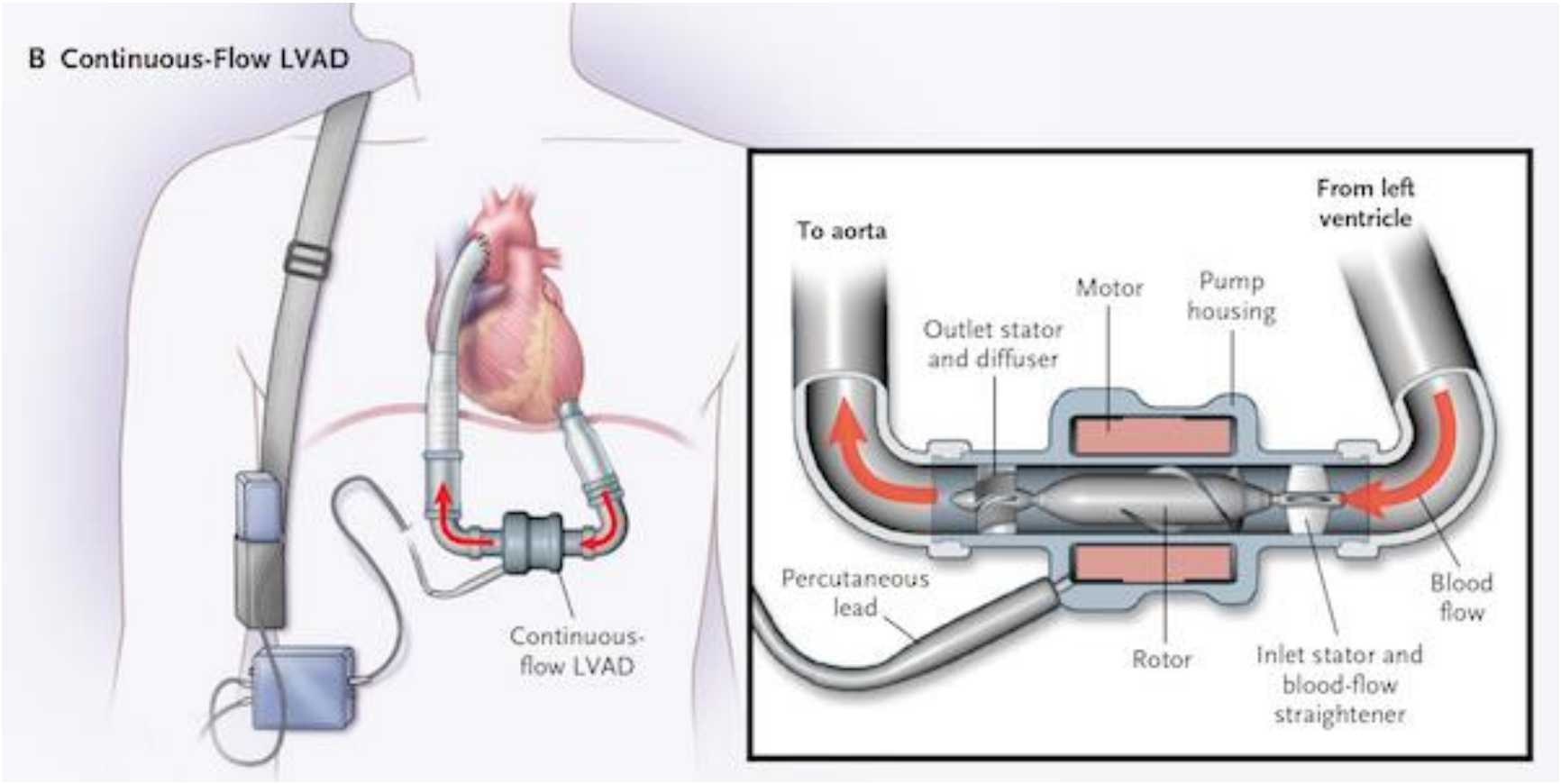
- A VAD is a Mechanical Circulatory Support (MCS) device designed to restore blood flow and improve survival, functional status, and quality of life for those suffering from advanced heart failure
- The device is implanted in parallel with the heart, taking over a majority of its circulatory function
- Multiple devices in use
- No age limit

Ventricular Assist Device

- Implanted in heart failure patients
- Augments the function of the ventricles in circulating blood
- Sometimes implanted as a temporary treatment, and sometimes used as a permanent solution to very low cardiac output



Auscultate over apex



Total Artificial Heart (TAH)

- Pump surgically implanted to provide biventricular circulatory support

VAD versus TAH

VAD and TAH differences

Ventricular Assist Device	Total Artificial Heart
Usually pulseless	Pulsatile
ECG shows native heart rhythm	ECG is meaningless since there is no heart
Pulse oximetry is inaccurate or absent	Pulse oximetry is accurate
Do not use NTG	Patients are ordered to use NTG for systolic blood pressure >140 mmHg
Consult your local EMS protocols or base hospital regarding whether to perform chest compressions on VAD patient	No compressions on TAH patients
You may cardiovert or defibrillate	Do NOT cardiovert or defibrillate
Must auscultate the left upper quadrant of the patient's abdomen for the "hum" of the VAD	The TAH's Freedom Driver is audible without a stethoscope, making a "galloping" type of sound
Usually have an ICD	Do not have an ICD
May be able to obtain a Mean Arterial Pressure (MAP) using a Doppler device only. Normal sphygmomanometer will not work. MAP should be from 70 – 85 mmHg.	Blood pressure is obtainable utilizing a normal sphygmomanometer.

DC Adapter

AC Adapter

HVAD® Controller

HeartWare Batteries and Charger