

The Landscape of Mechanical Circulatory Support.

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Presenter Disclosure Information

- I **will not** discuss off label use or investigational use in my presentation.
- I **have** financial relationships to disclose:
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Terminology and Classification of MCS

• Ventricle Supported

- Left ventricular assist device
- Right ventricular assist device
- Biventricular assist device
- Total artificial heart

• Anatomical Position

- Extracorporeal pump
- Intracorporeal pump
- Paracorporeal pump
- Orthotopic TAH

• Intended Use

- Duration of support
 - Short-term MCS
 - Patient remains within hospital
 - Long-term, “Durable” MCS
 - Patient discharged to home
 - “hands free” untethered mobility
- Indication
 - Bridge to recovery
 - Bridge to transplant
 - Destination therapy

• Pump Mechanism

- Pulsatile, volume displacement
 - Pneumatic or electrical actuation
- Continuous-flow rotary pump
 - Axial design
 - Bearing-supported rotor
 - Magnetic suspension
 - Centrifugal design
 - Passive or active magnetic levitation
 - Hydrodynamic (fluid forces)



Surgical Implantation

Thoratec HeartMate II
MicroMed DeBakey HeartAssist 5
MicroMed DeBakey Pediatric
Jarvik 2000
Berlin Heart Incor
HeartWare HVAD
Terumo DuraHeart

Thoratec HeartMate XV
Thoratec IVAD
Syncardia CardioWest TAH-t
Thoratec pVAD
Berlin Heart Excor
Berlin Heart Excor Pediatric

Continuous-flow Pump

<p>Abiomed Impella LD 5.0</p> <p>Levitronix CentriMag</p>	<p>Abiomed BVS 5000</p> <p>Abiomed AB 5000</p>
<p>Abiomed Impella LP 2.5</p> <p>Abiomed Impella LP 5.0</p> <p>TandemHeart pVAD</p> <p>ECMO</p>	<p>IABP</p> <p>Short</p>

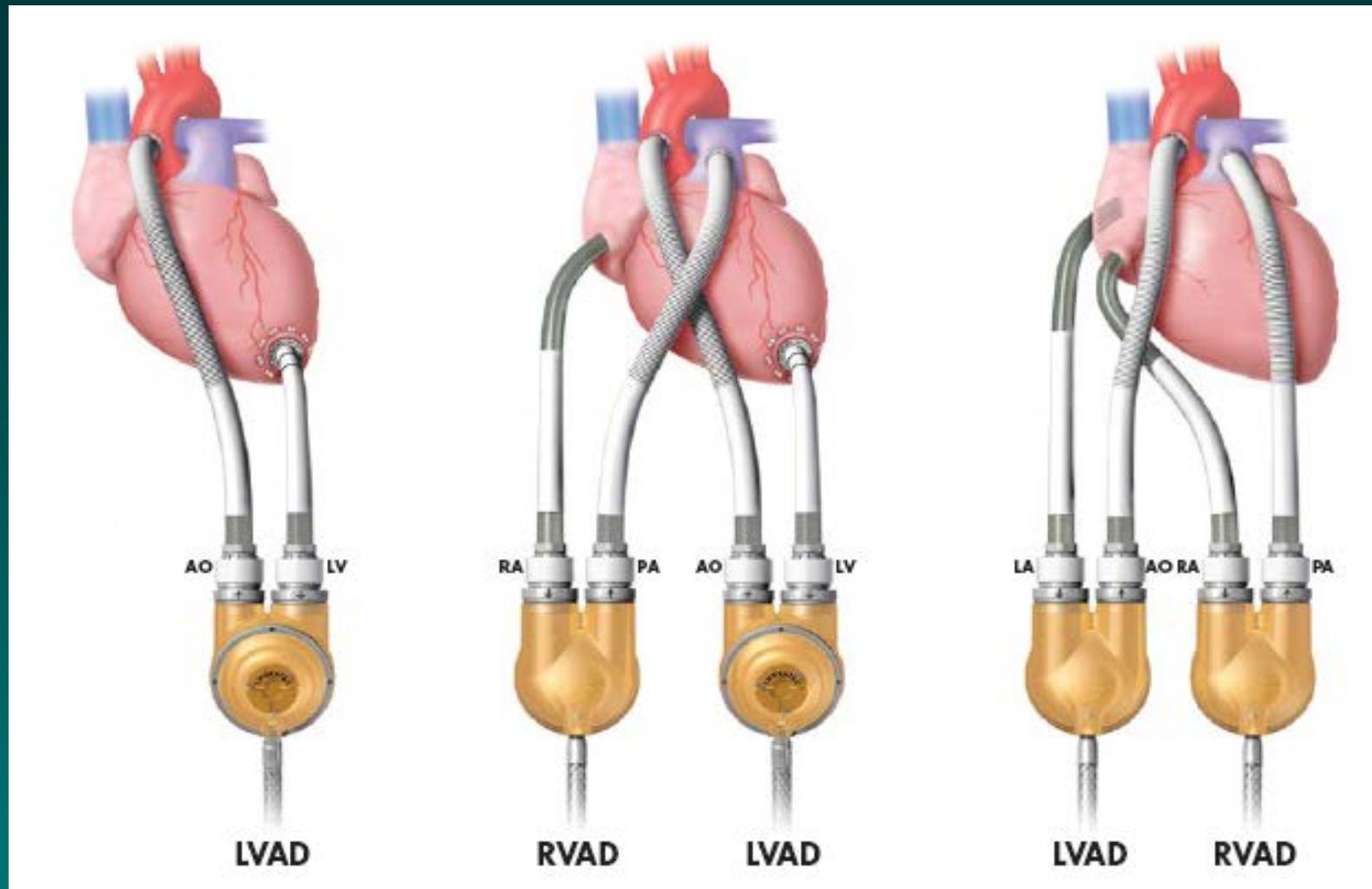
Pulsatile Volume Displacement Pump

Duration of Use

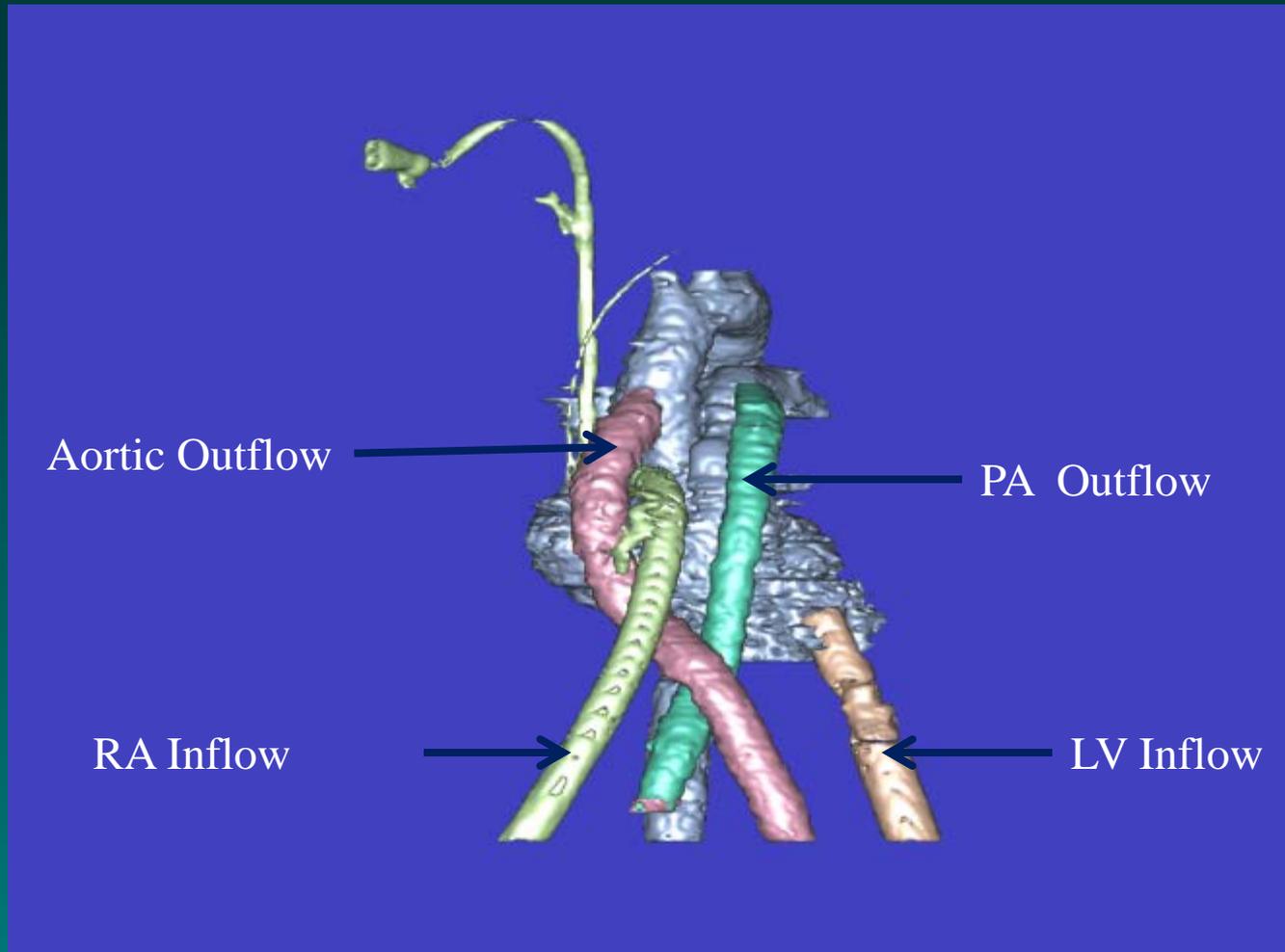
Long

Non-operative Implantation

Thoratec Paracorporeal VAD



Thoratec PVAD BiVAD

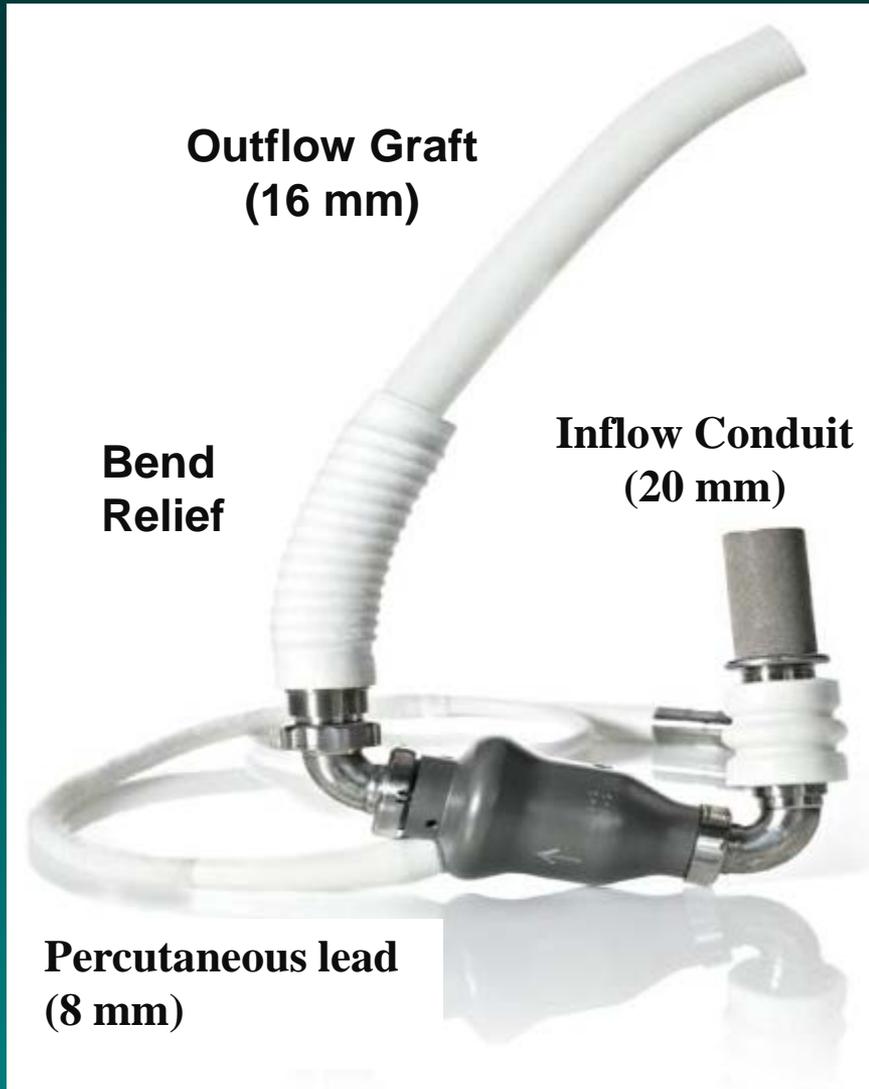


Criteria for Durable “*Long-term*” Mechanical Circulatory Support (MCS) Designation

- Durable (reliable performance for > 3-5 years)
- Intracorporeal
 - requires operative placement or minimally-invasive techniques
 - Device design intended for both:
 - Bridge to transplantation**
 - Destination therapy**
- “Hands free” untethered mobility > 12 hours / day
 - distinguishes paracorporeal systems from intracorporeal systems
 - minimize requirement for frequent battery changes
 - quiet operation
- Discharge to home capabilities

HeartMate II

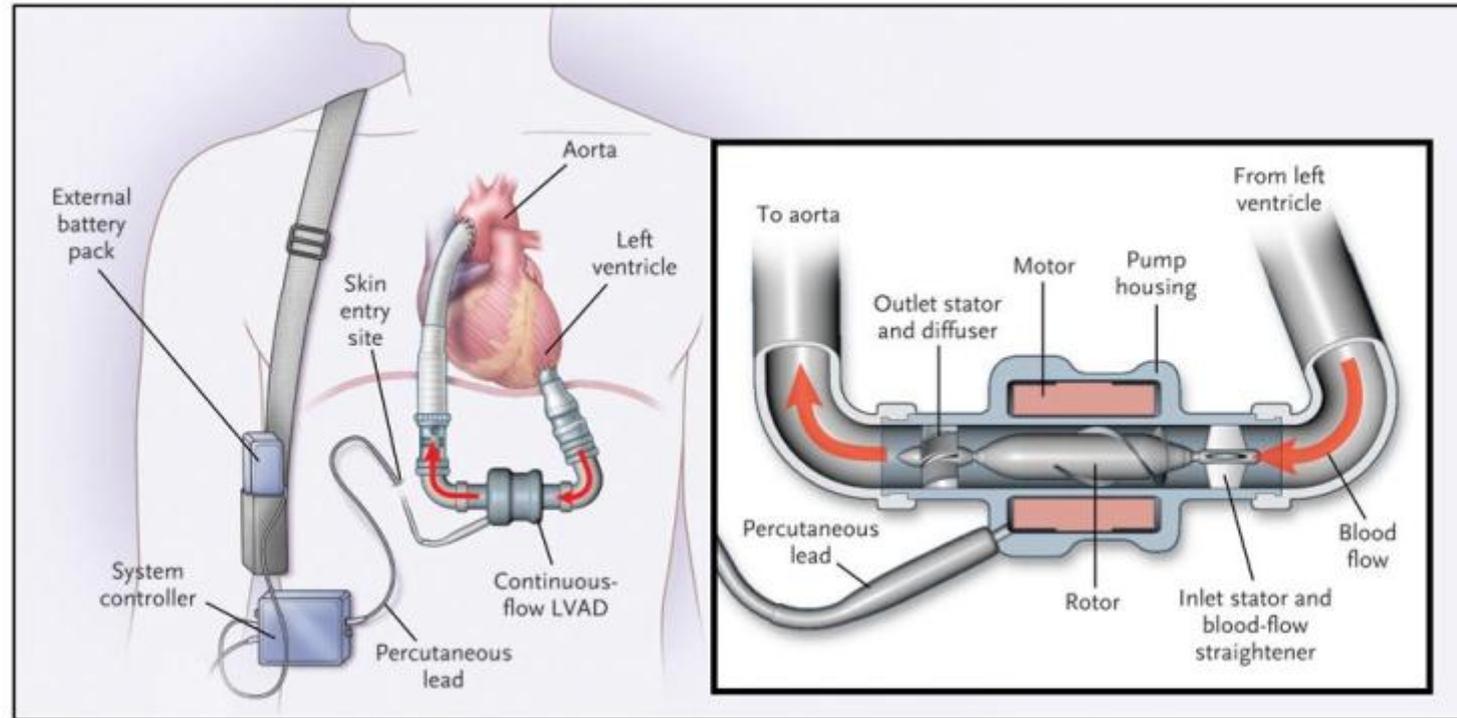
Pump External View



Flex Section

- Woven polyester graft
- Titanium ring
- Preclotting slots
- Silastic sleeve

HeartMate II Continuous Flow Pump



Advantages

- No heart valves
- No flexible diaphragm
- No large housing to accommodate pump “stroke volume”
- Fewer moving parts
- Potential for biventricular application

Disadvantages

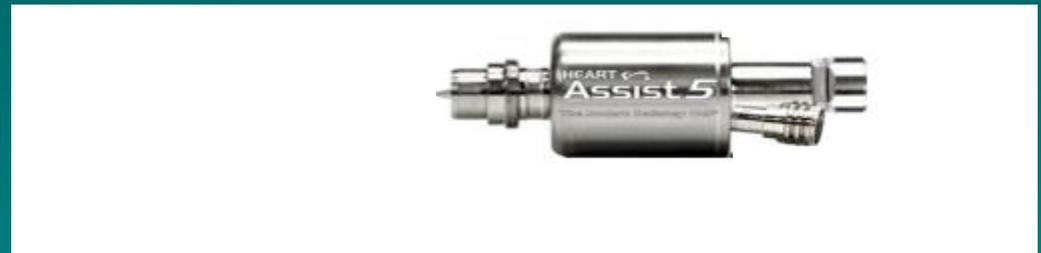
- Minimal pulse
- Significant AI if pump malfunction occurs
- Operated in fixed mode speed may limit cardiac output
- Afterload dependent

HeartMate II LVAD



Continuous Flow Rotary Pumps with Axial Design

- **Thoratec HeartMate II**
 - FDA approved for BTT (May 2008) and DT (Dec 2010)
- **Jarvik 2000 FlowMaker**
 - US pivotal trial in progress
- **MicroMed DeBakey HeartAssist 5**
 - US pivotal trial in progress

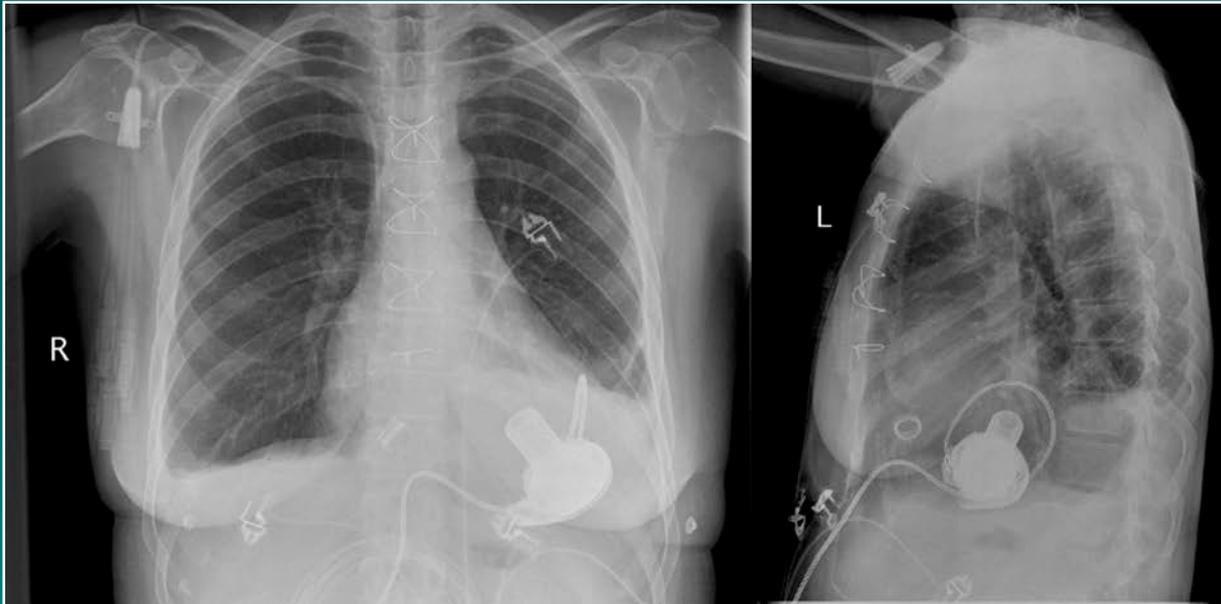
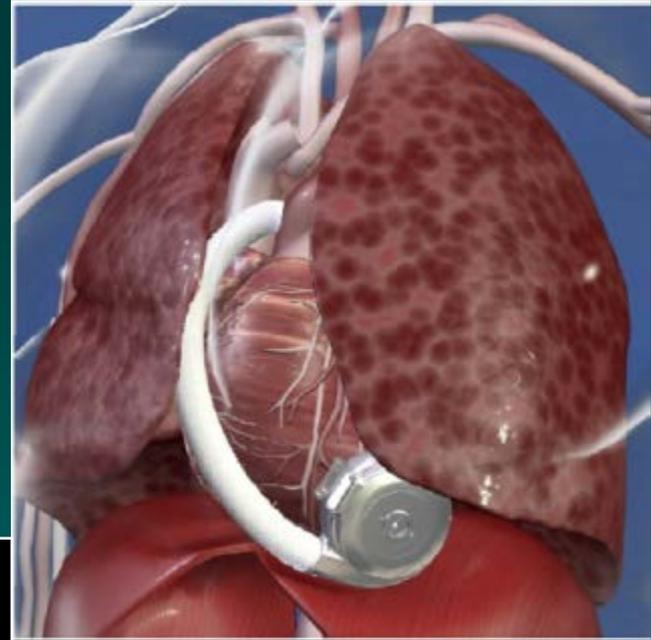


Continuous Flow Rotary Pumps with Centrifugal Design

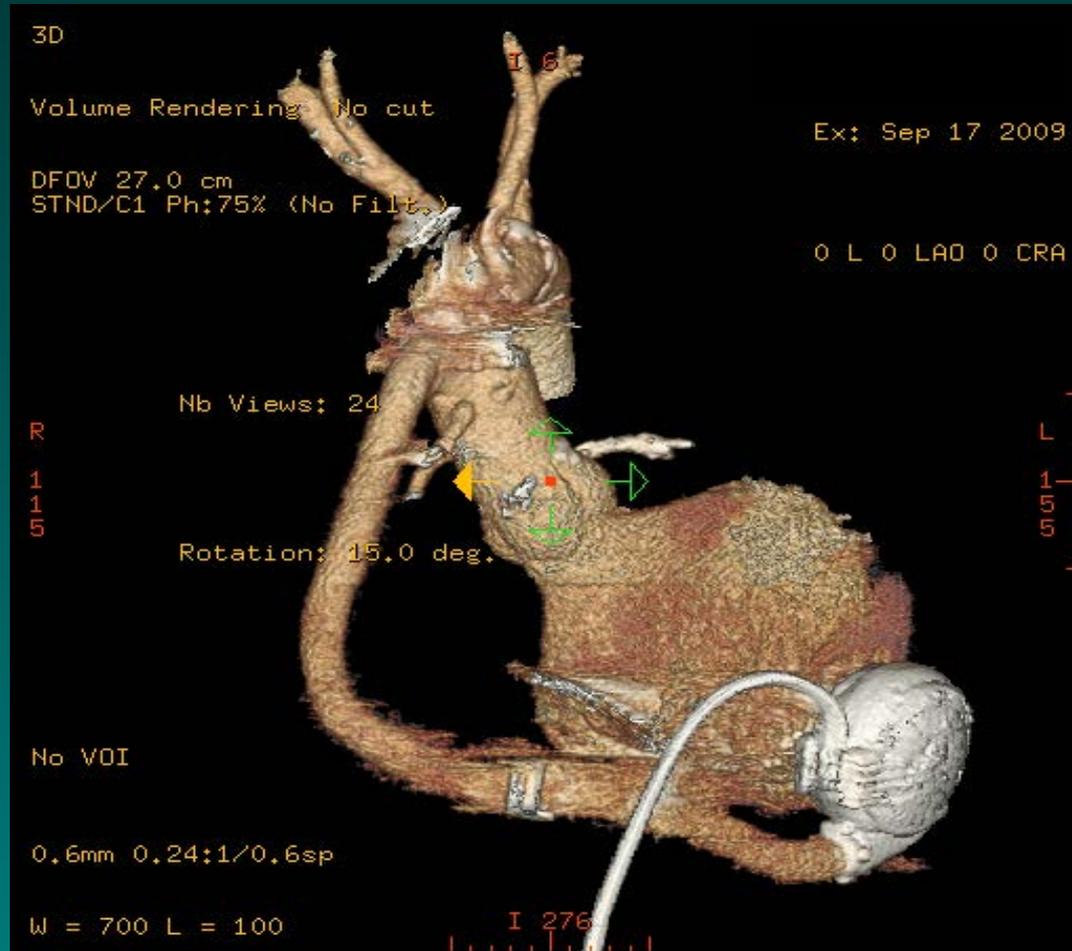
- **HeartWare HVAD**
 - Completed European / International testing for CE mark
 - US feasibility / pivotal trial completed for BTT evaluation. Pivotal trial for DT evaluation in progress.
- **EvaHeart LVAD** EvaHeart Medical USA, Clinical testing in Japan
 - US Pilot trial



HeartWare



HeartWare LVAD



Levitation Systems

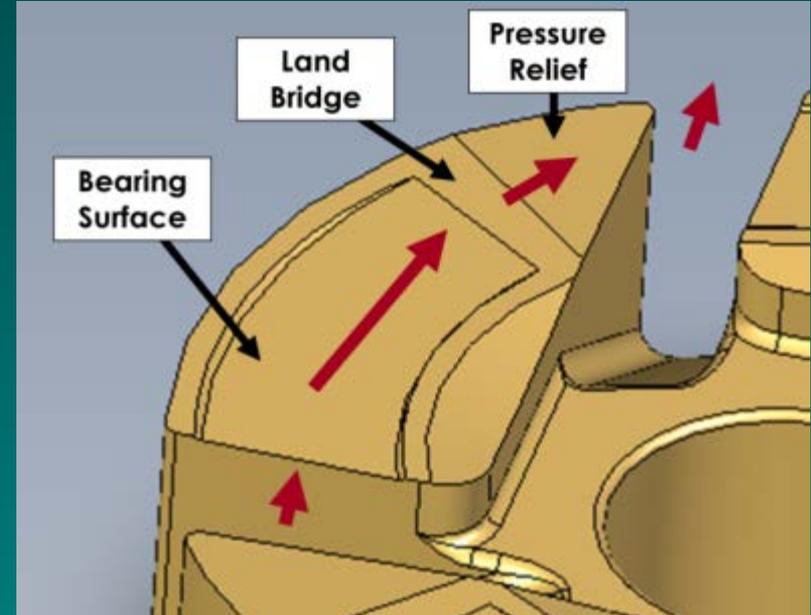
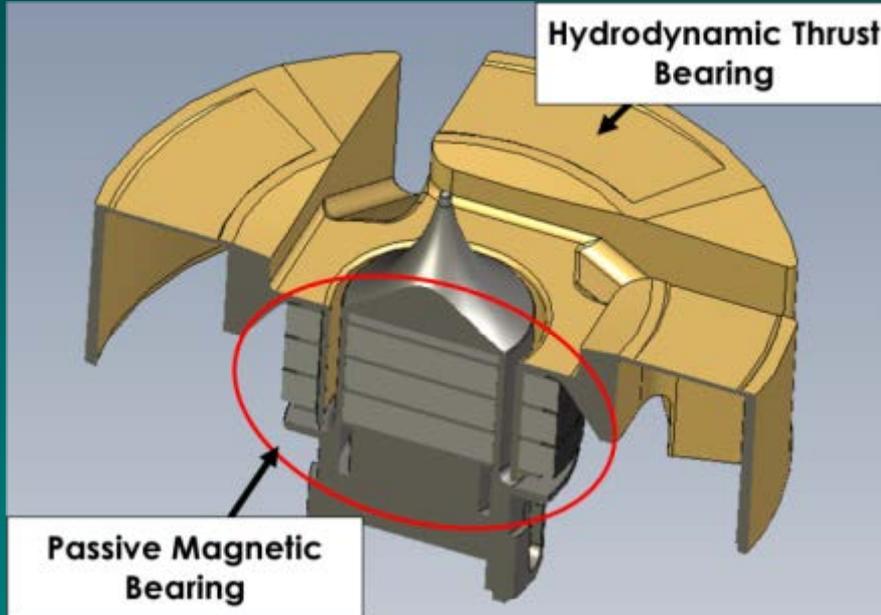


Hybrid Levitation System

- Passive magnetic levitation
- Hydrodynamic levitation

Electrical input needed for:

- Motor stator



Summary

- Current Mechanical Circulatory Support options with durable devices require traditional open heart surgery techniques.
- Considerations have to be made for other acquired abnormalities such as PFO and tricuspid valve and aortic valve insufficiency.
- Typical perioperative adverse events following cardiac surgery such as bleeding, arrhythmias, right heart failure and infection are commonplace.