

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 MCSD

- **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 XVE
Thoratec IVAD
Syncardia CardioWest TAH-t
Thoratec pVAD
Berlin Heart Excor
Berlin Heart Excor Pediatric



Continuous-flow Pump

Abiomed Impella LD 5.0
Levitronix CentriMag

Abiomed BVS 5000
Abiomed AB 5000

Abiomed Impella LP 2.5
Abiomed Impella LP 5.0
TandemHeart pVAD
ECMO

IABP

Short

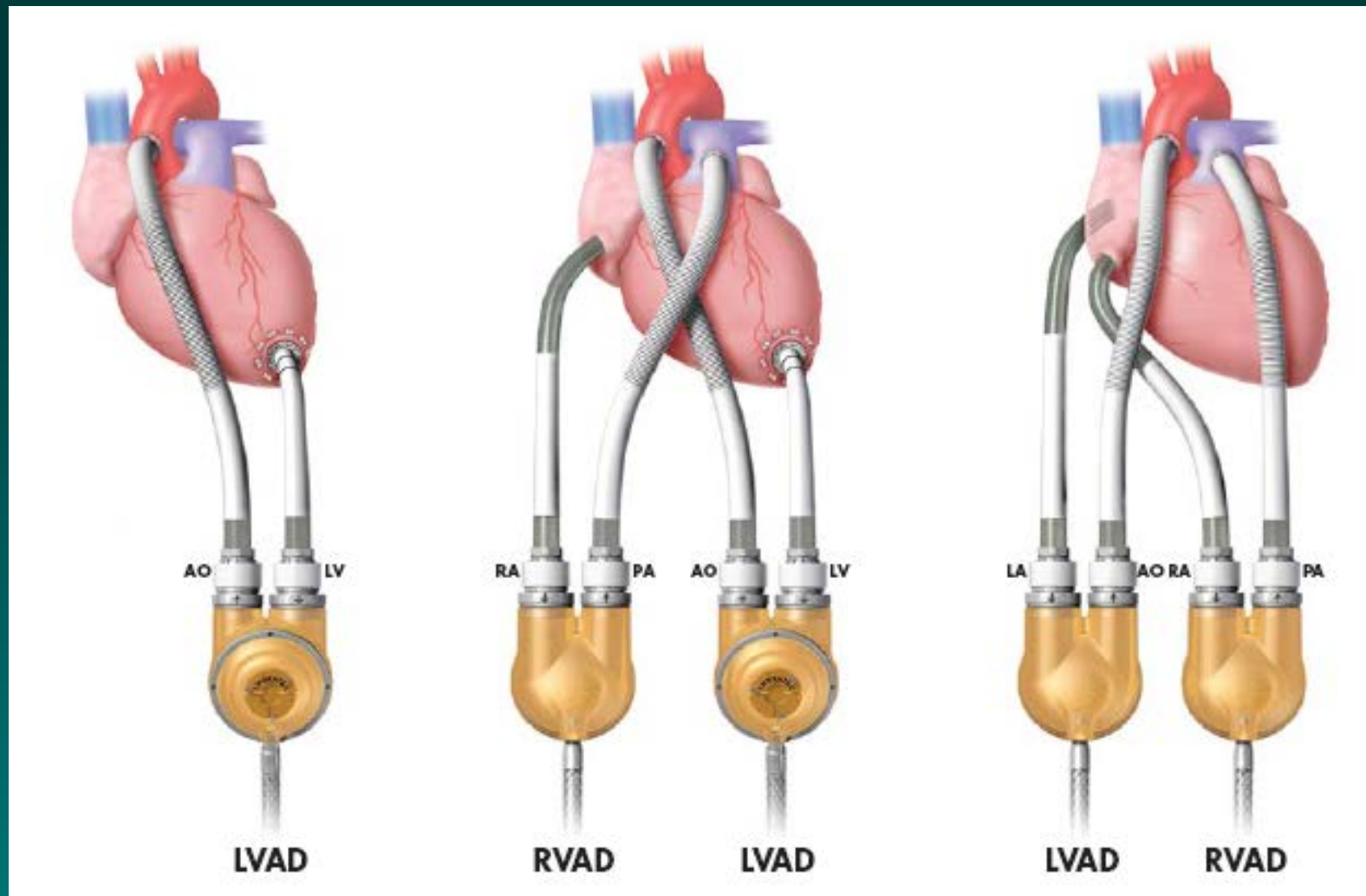
Long

Duration of Use

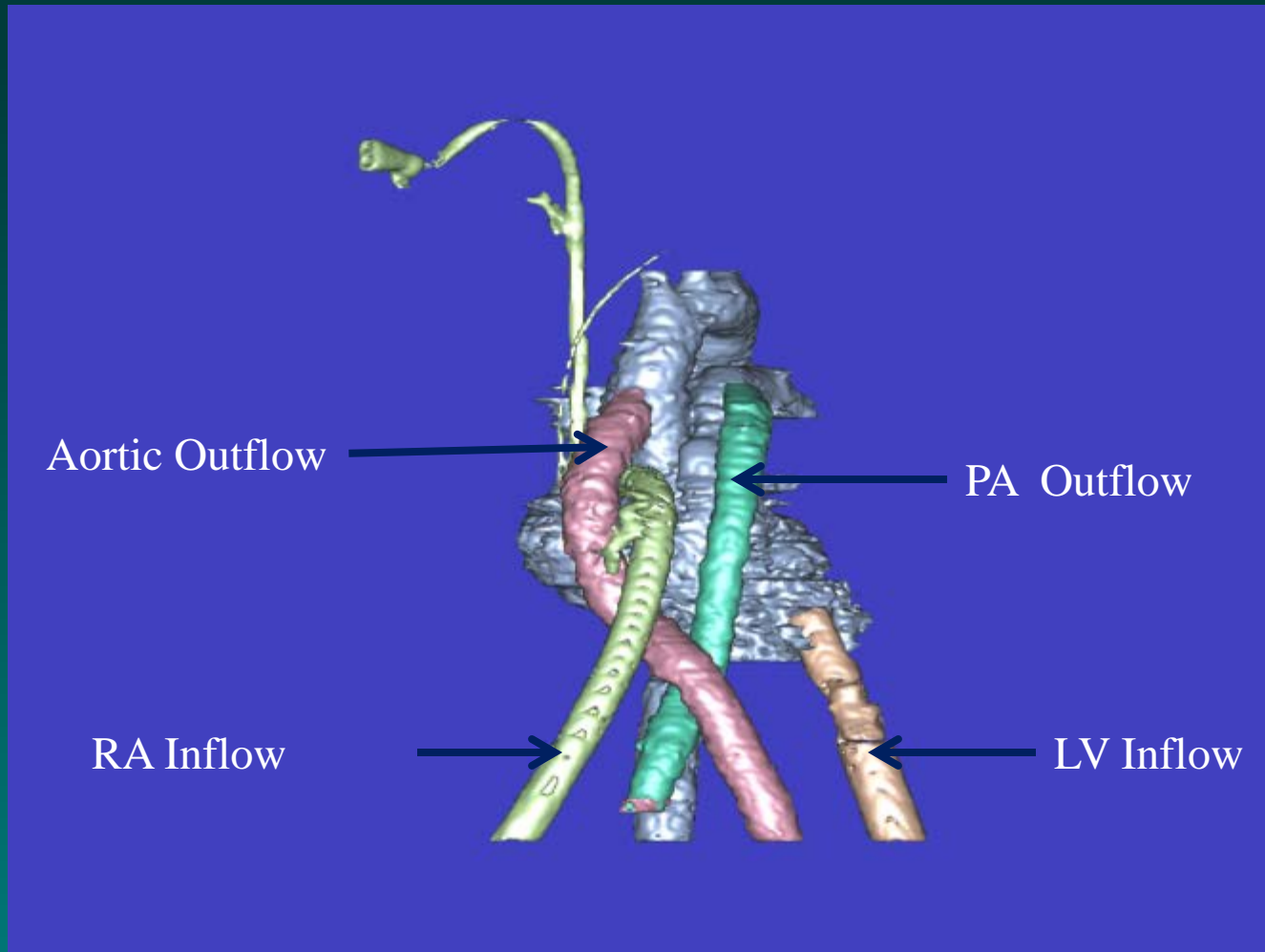
Pulsatile Volume Displacement Pump

Non-operative Implantation

Thoratec Paracorporeal VAD



Thoratec PVAD BiVAD

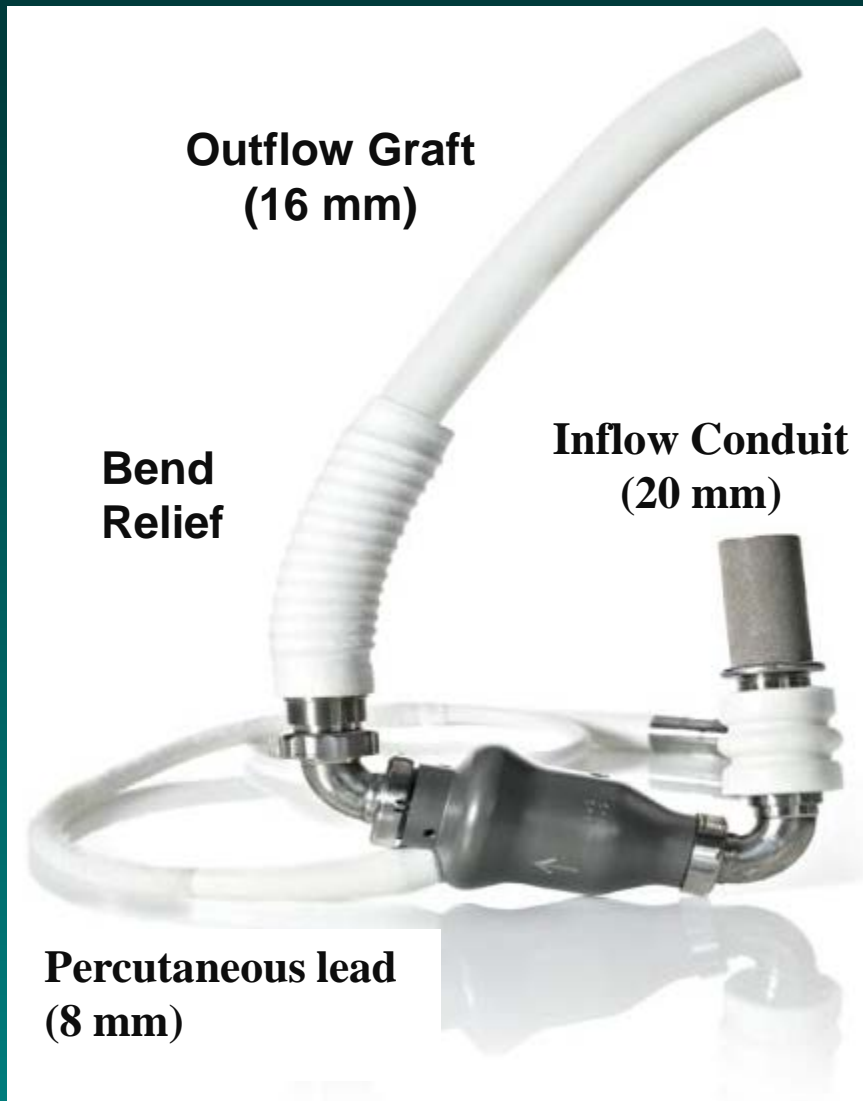


Criteria for Durable “*Long-term*” Mechanical Circulatory Support (MCS) Designation

- 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

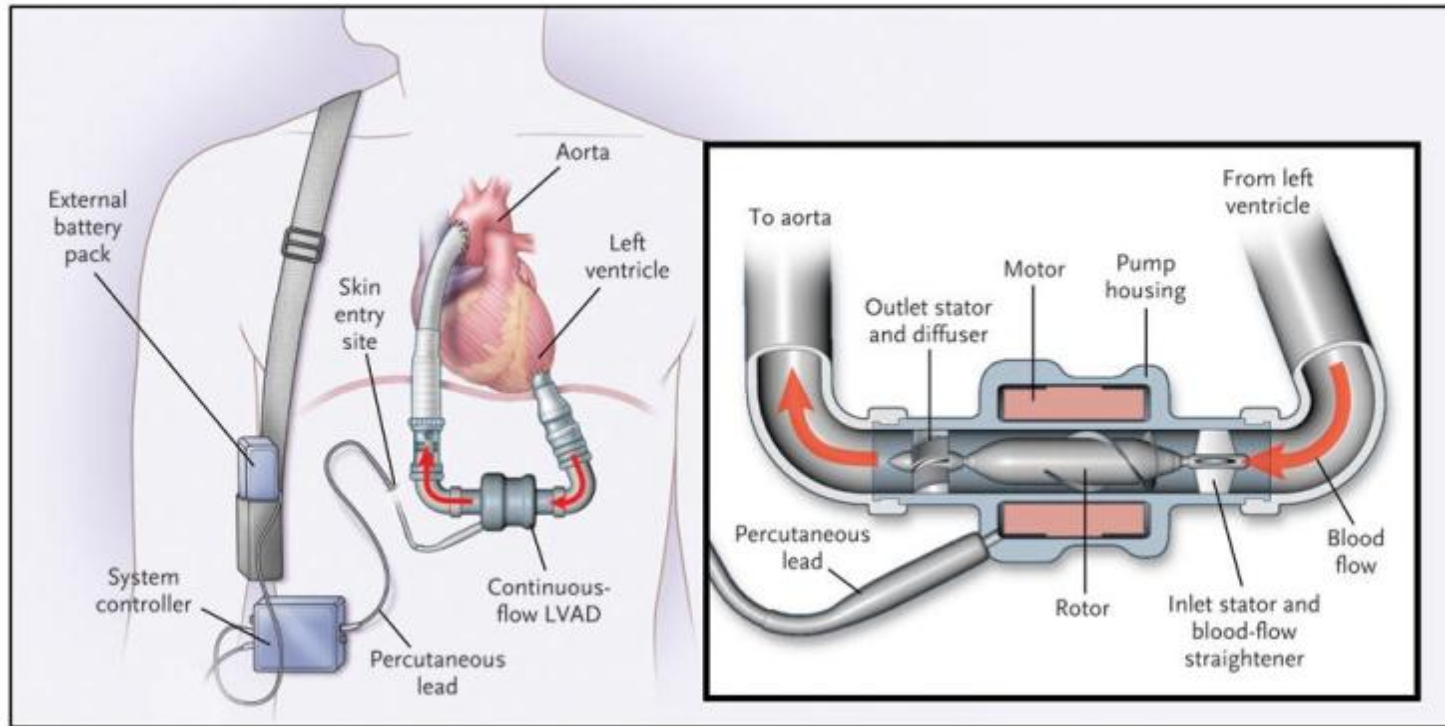
Pump External View



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

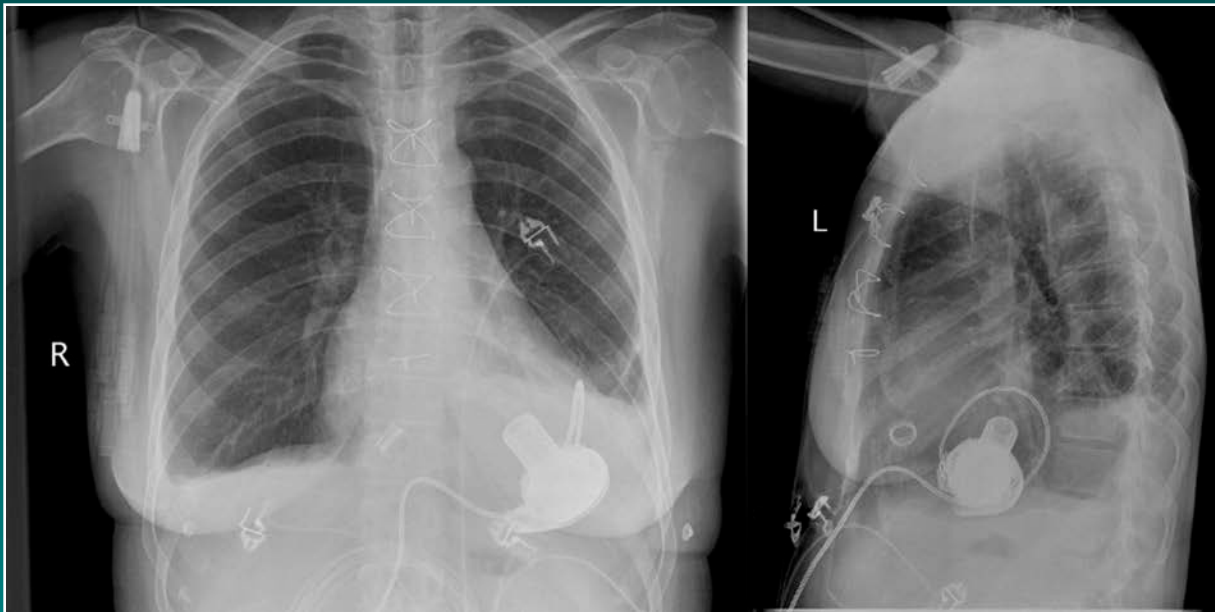


Continuous Flow Rotary Pumps with Centrifugal Design

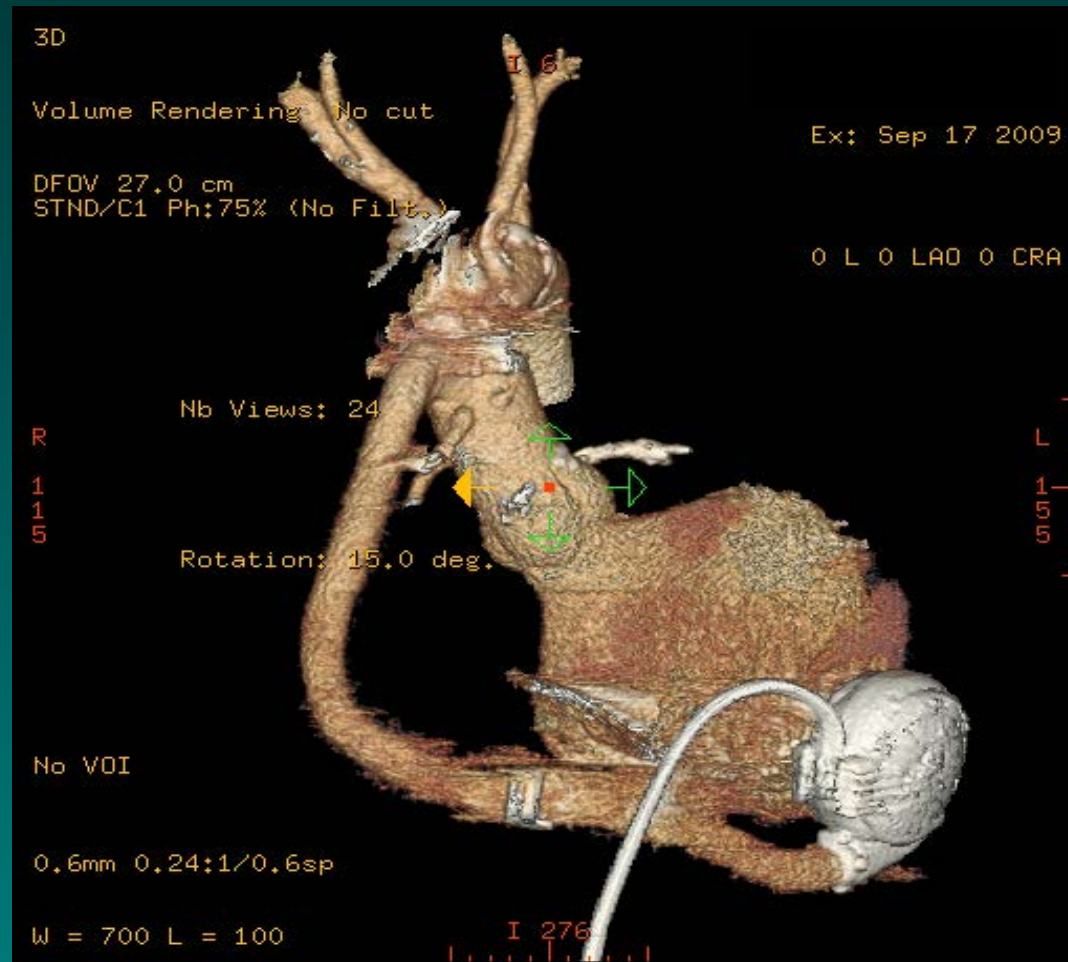
- **HeartWare HVAD**
 - Completed European / International testing for CE mark
 - US feasibility / pivotal trial completed for BTT evaluation. Pivotal trial for DT evaluation in progress.
- **EvaHeart LVAD** EvaHeart Medical USA, Clinical testing in Japan
 - US Pilot trial



HeartWare



HeartWare LVAD



Levitation Systems

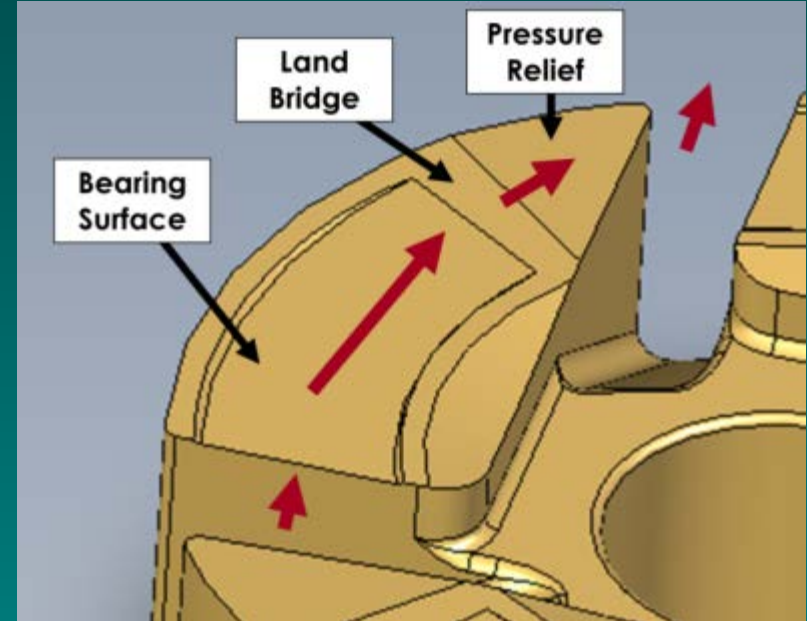
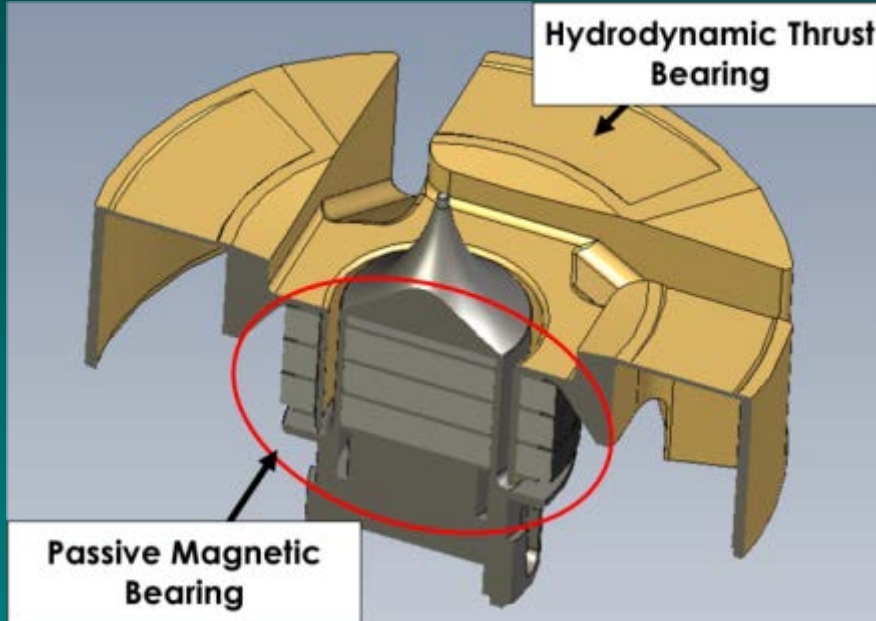


Hybrid Levitation System

- 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.