

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

SURGICAL CONSIDERATION IN HEART FAILUR

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**NON TRANSPLANT
SURCICAL
OPTIONS FOR
HEART FAILUR**

***CORONARY
REVASCULARIZATION***

***PERCUTANEOUS
MITRAL VALVE
REPAIR***

MITRA CLIP



***EMERGING
BIOMEDICAL DEVICES
FOR
HEART FAILURE***

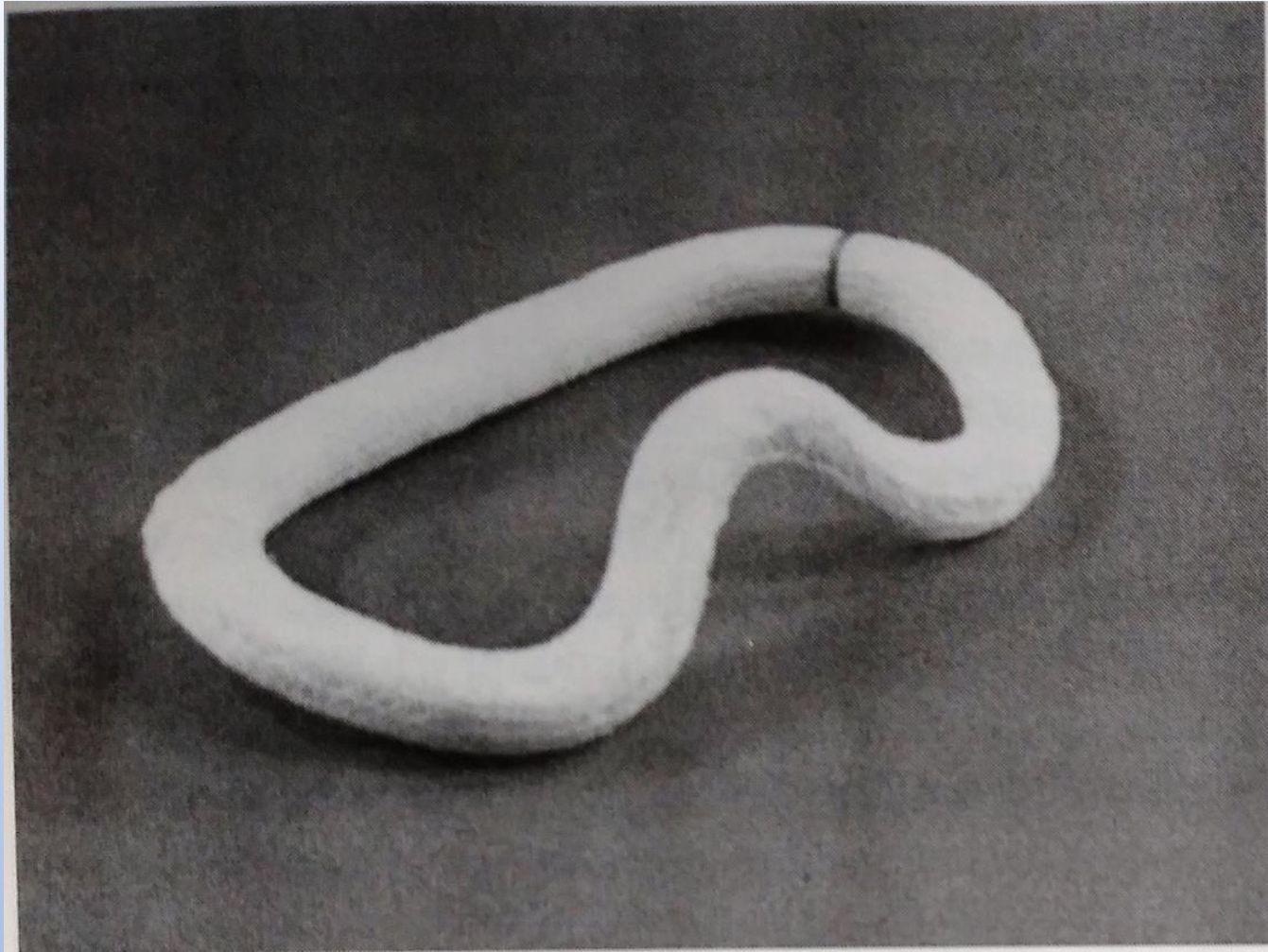


Figure 69-5. Oblique view of the Geoform mitral annuloplasty ring. Note the posterior ring design element which reverses the adverse changes in the posterior mitral annulus associated with geometric mitral regurgitation.

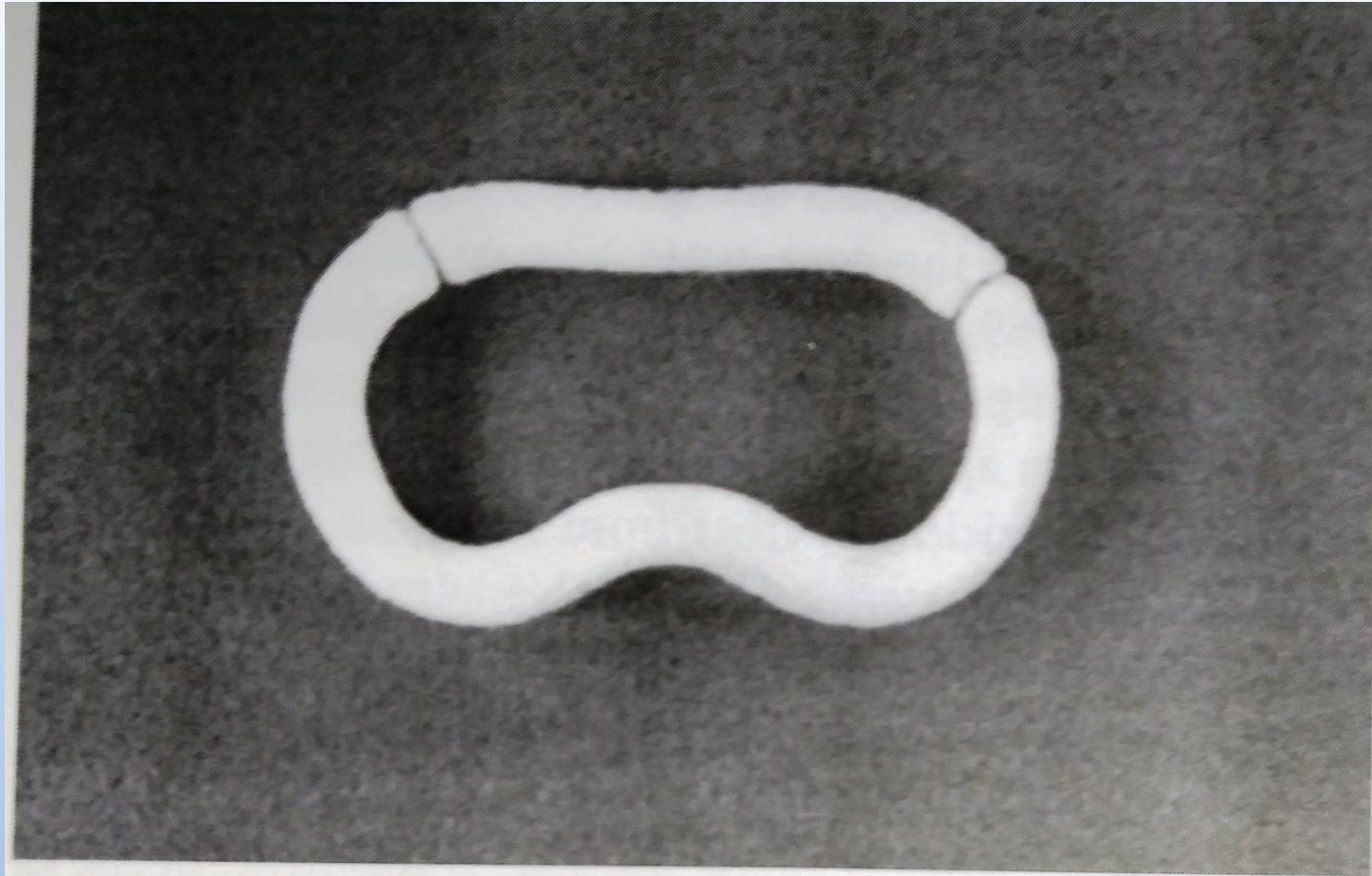


Figure 69-6. Superior view of the Geoform mitral annuloplasty ring. The three-dimensional cross-sectional area is not restrictive to atrial blood flow.

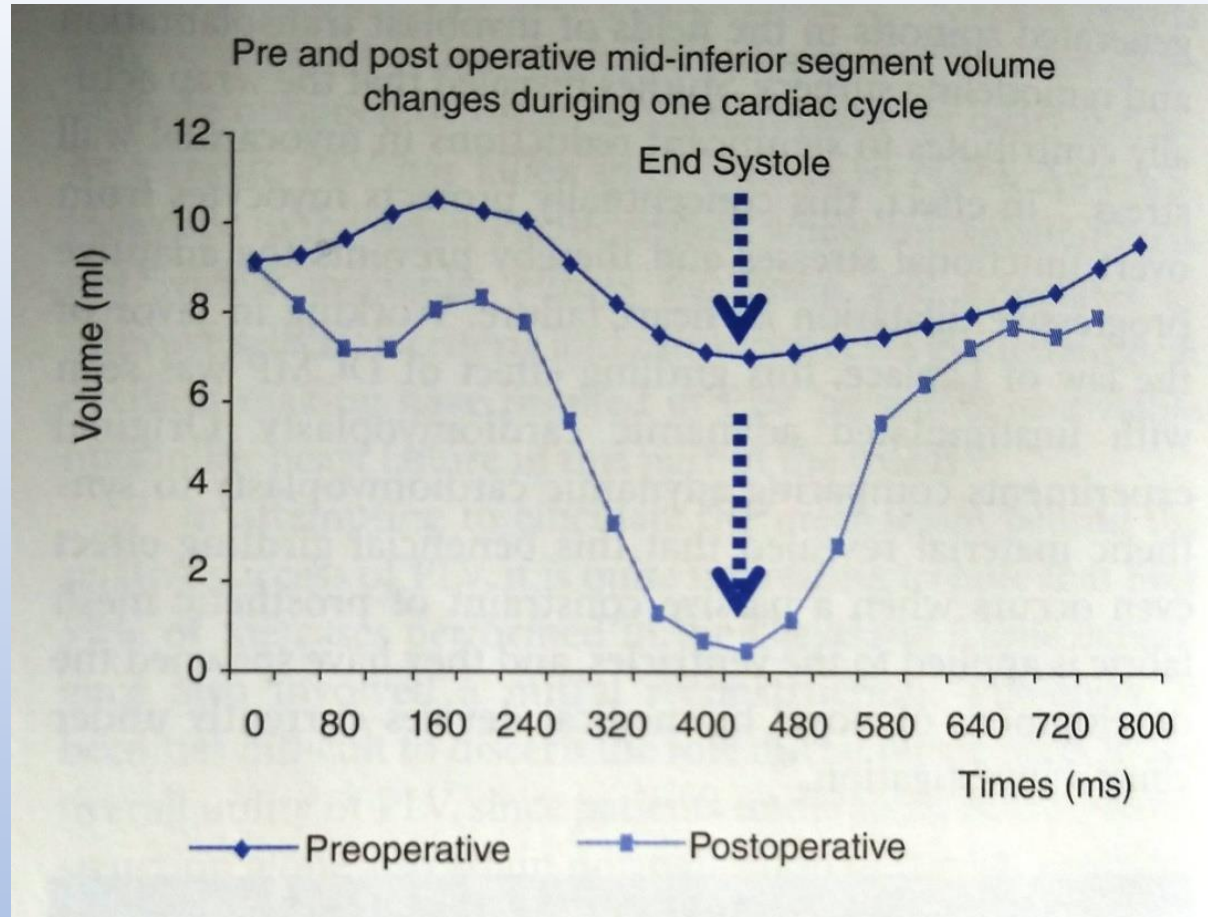


Figure 69-8. Left ventricular volume changes obtained on post-operative day 5 following geometric mitral valve repair. Increases in regional EF in the infero-basal wall are shown which are the opposite of the decreased EF expected following MVR based on historical teaching. (Courtesy of Nadia Nathan, MD.)



Figure 69-7. Postoperative three-dimensional echocardiography of a mitral repair performed using the Geoform mitral annuloplasty ring. Note the apposition of the central areas of the anterior and posterior mitral valve leaflets which help to establish a zone of coaptation and abolish mitral regurgitation.

***GEOMETRIC
MITRAL
RECONSTRUCTION***

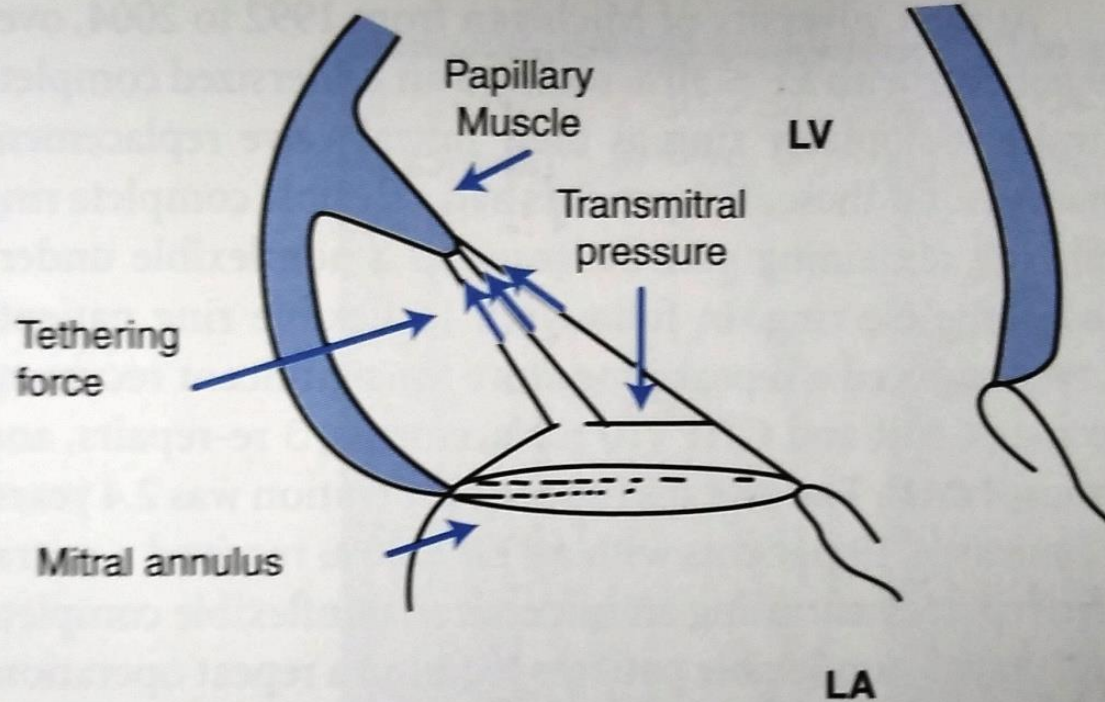


Figure 69-1. Various forces exerted on mitral valve leaflets are provided by the mitral valve apparatus, papillary muscles, and important three-dimensional relationships in the ventricle itself of all of the associated structures. Geometric mitral regurgitation results from a combination of annular dilatation, papillary muscle displacement, increased leaflet tethering forces, and weakened leaflet closing forces.

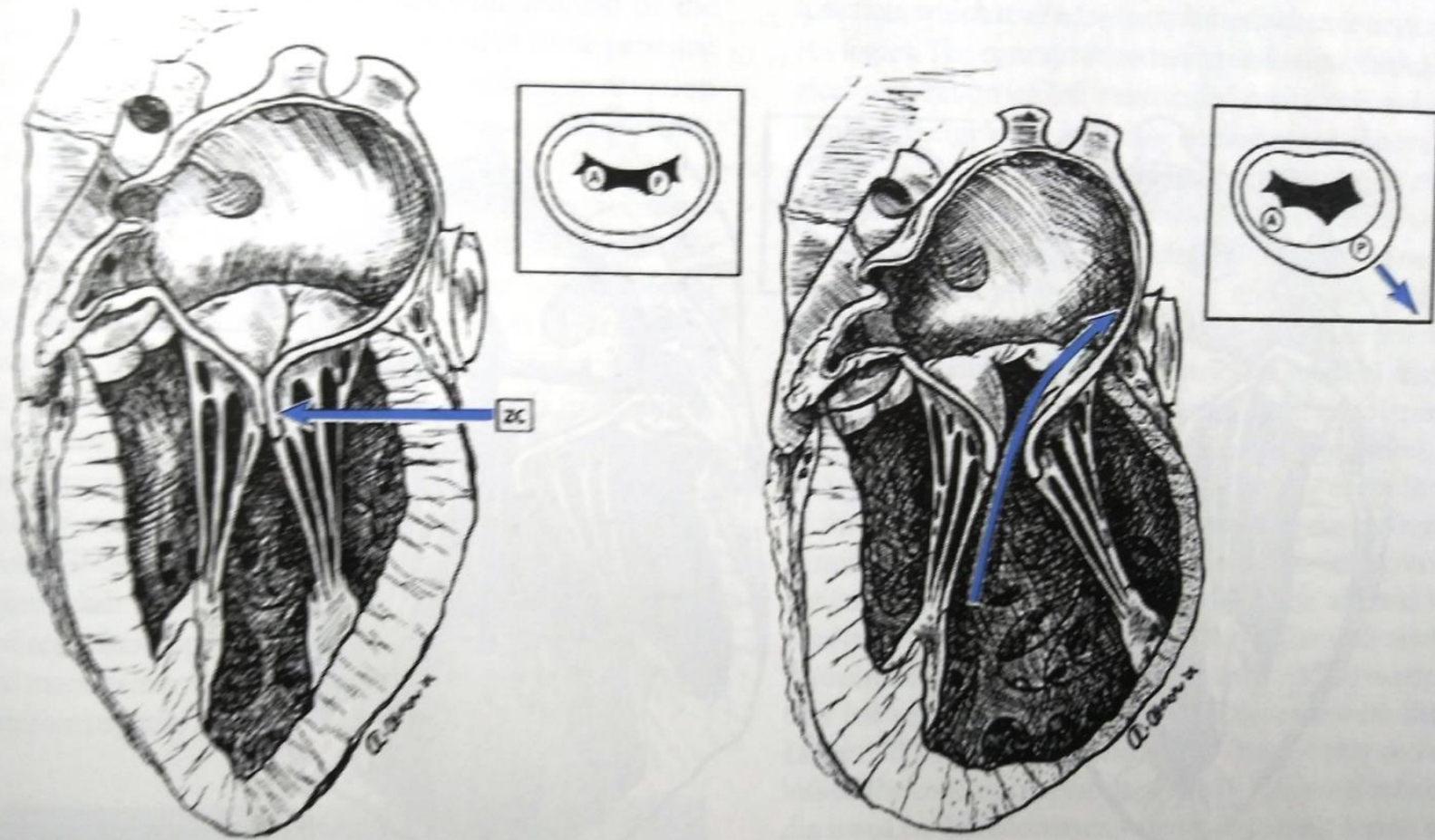


Figure 69-2. In ischemic cardiomyopathy, changes within the left ventricle may be asymmetrical and still lead to functional mitral regurgitation. With ischemic damage and thinning of the ventricular wall, there is lateral tethering, displacement of the papillary muscle, and loss of the zone of coaptation (ZC), resulting in an eccentric jet of mitral regurgitation. This illustrates the concept that ischemic mitral regurgitation results from lateral wall dysfunction that if left untreated, will progress to global left ventricular dysfunction and severe heart failure.

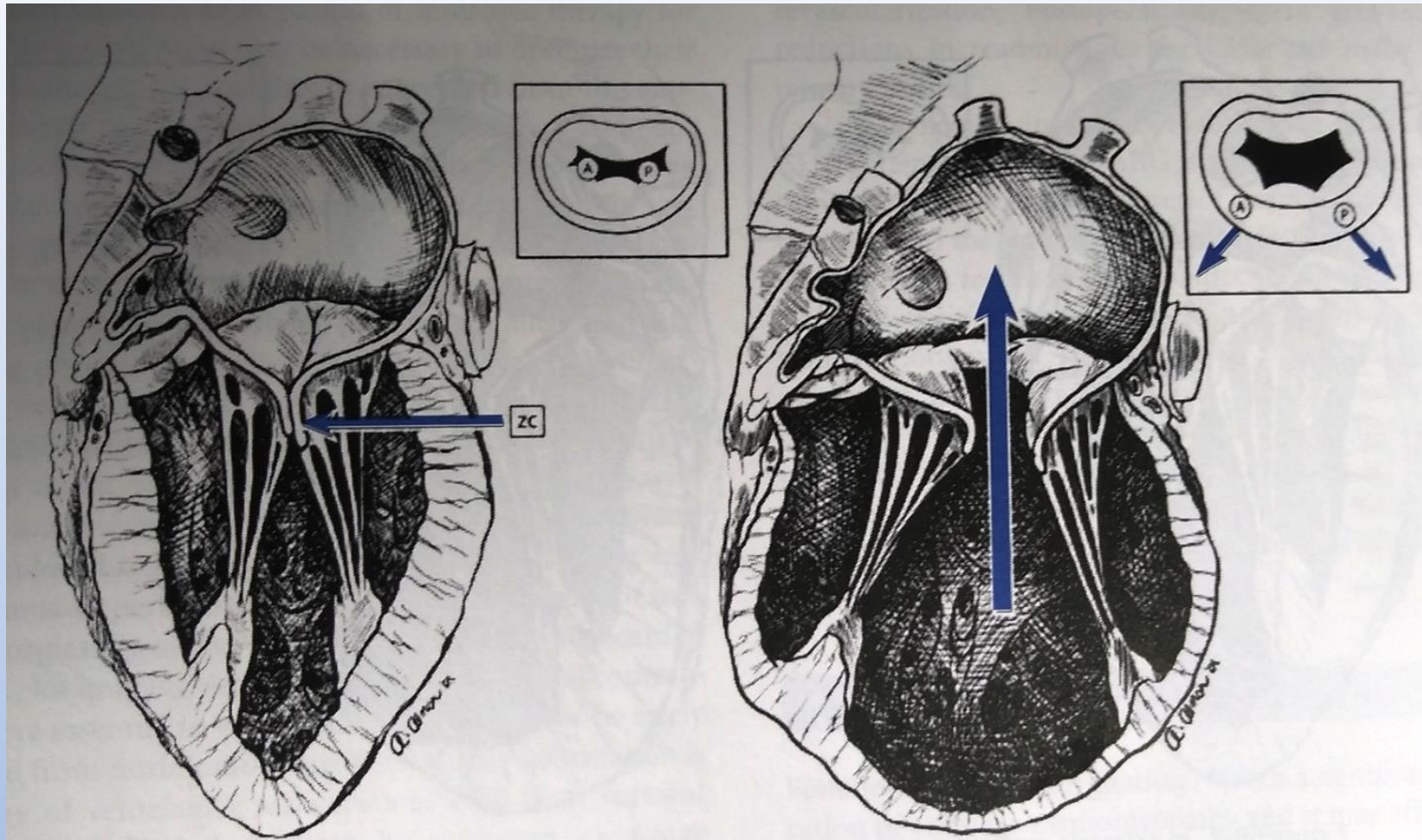


Figure 69-3. In non-ischemic cardiomyopathy note the geometric changes that occur from the normal to the failing left ventricle. With the ventricular and annular dilatation of heart failure, the mitral leaflets cannot adequately cover the enlarged mitral orifice, resulting in the loss of the zone of coaptation (ZC). Geometric mitral regurgitation results from a combination of annular dilatation, papillary muscle displacement, increased leaflet tethering forces, and weakened leaflet closing forces.

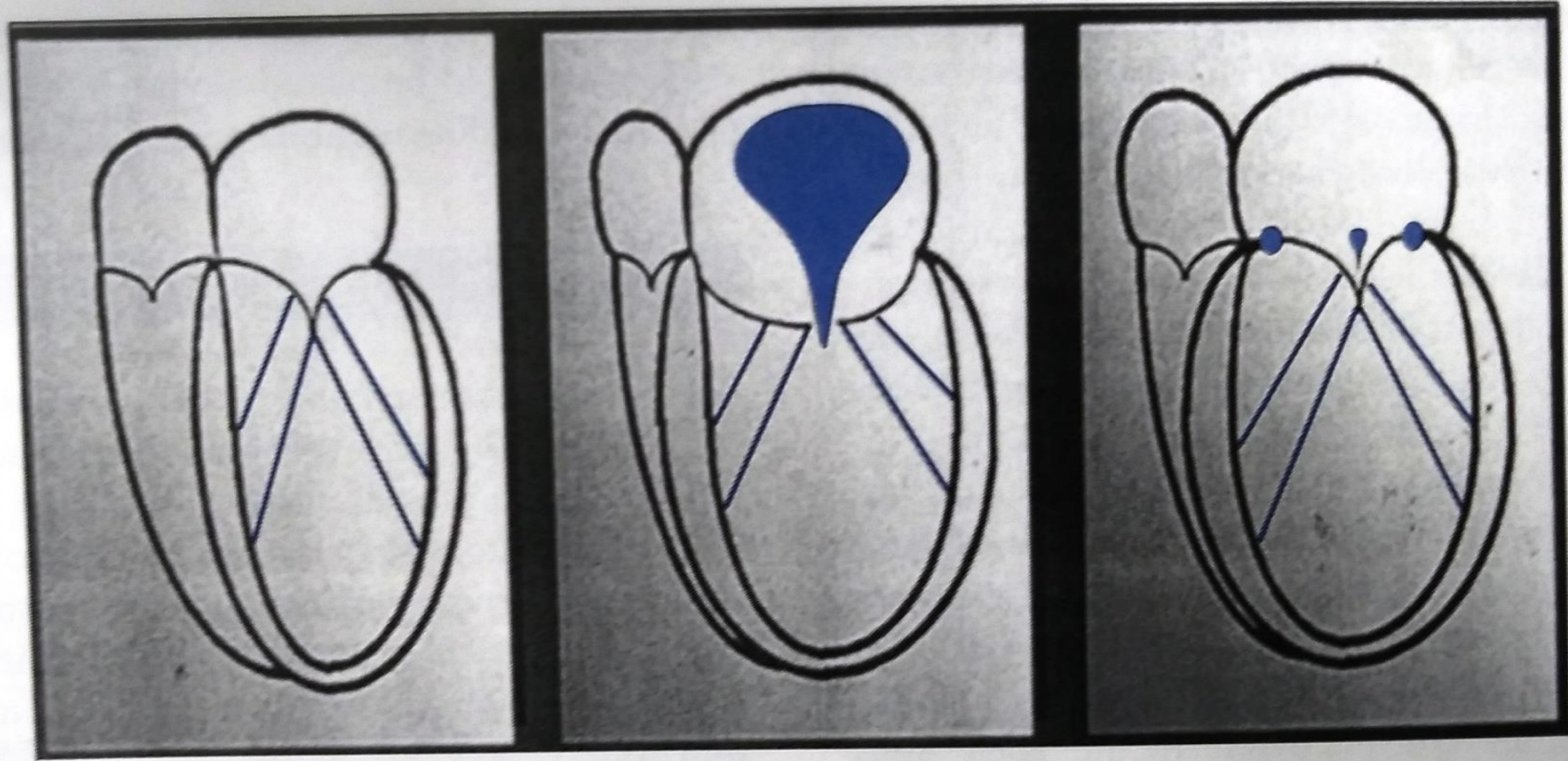


Figure 69-4. Geometric mitral reconstruction for heart failure. Successful augmentation of the zone of coaptation and prevention of recurrent MR can be achieved with placement of an undersized circumferential annuloplasty ring performed with multiple annular sutures. Note the changes in the relationship of the papillary muscles in the left ventricle in the new geometry following mitral repair.

***PARTIAL LEFT
VETRICULECTOMY***

- CARDIAC TRANSPLANTATION

- BARNARD-1967, *FIRST IN HUMAN*

- SHUMWAY.1970 ENDOMYOCARDIAL BIOPSY 1973

- IMMUNOSUPPRESSIVE THERAPY 1981

- 2500 TX/YEAR

- LIMITED DONOR ORGAN

- COST

- GOOD RESULT OP 5-10% MORTALITY 86% ONE YEAR SURVIVAL

HEART LUNG

TRANSPLANTATION

***CURRENT OPTIONS
FOR MECHANICAL
CIRCULATORY SUPPORT***

***EXTRACORPOREAL
MEMBRAN OXIGENATION
(ECMO)***

SHORT TERM SUPPORT


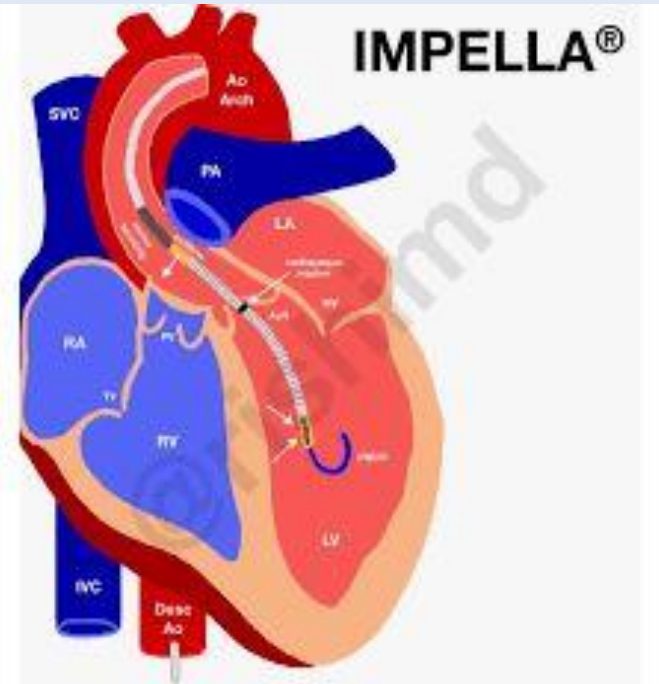
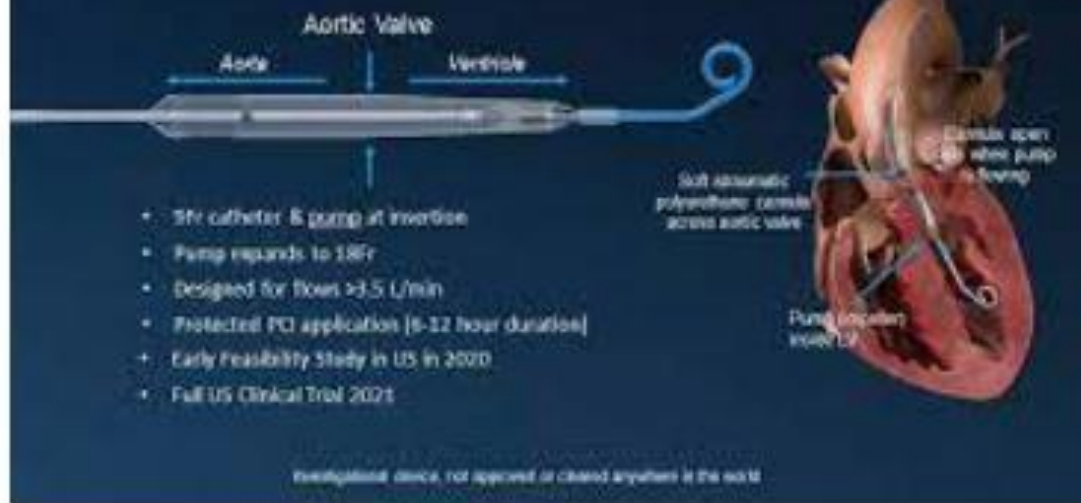
- VENO-VENOUS LUNG FAILUR
- VENO-ARTERIAL CPB
- CANNULATION  { PERIFERAL
CENTRAL



FIGURE 62-2 The catheter-based hemopump first revealed the safety and feasibility of high-speed continuous-flow circulatory support. (Used with permission from Dr. Richard Wampler.)

Impella ECP™ "Expandable CP"



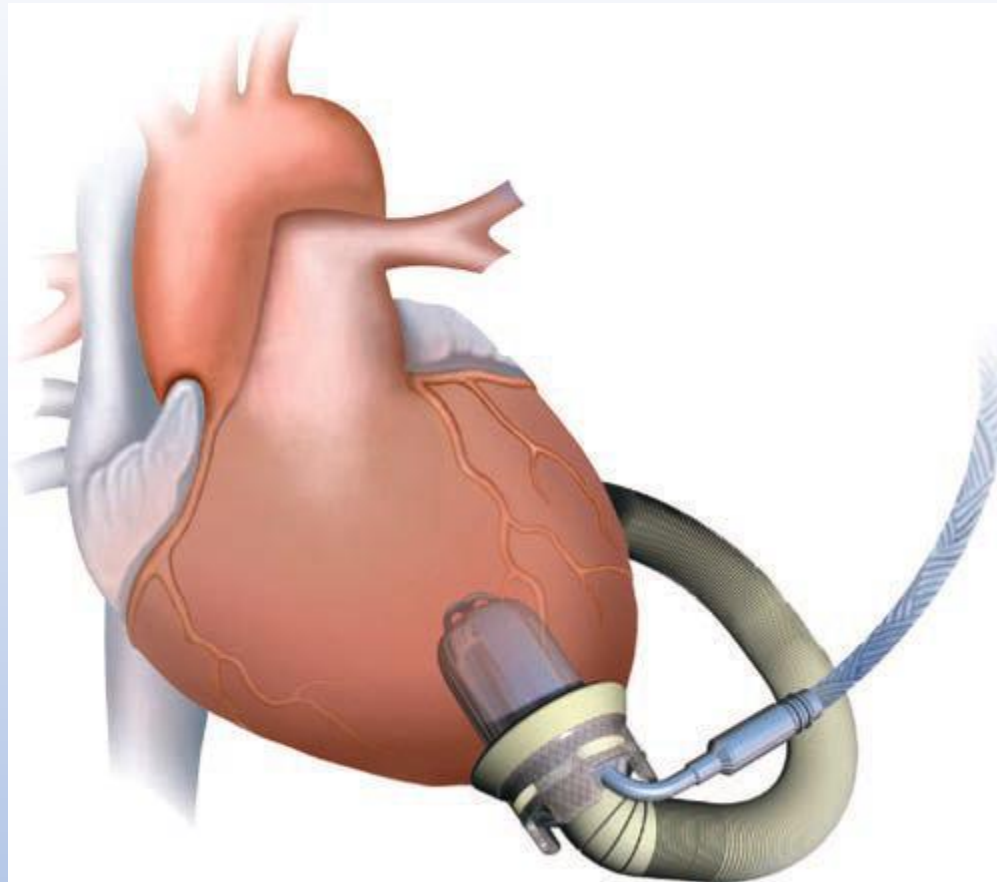
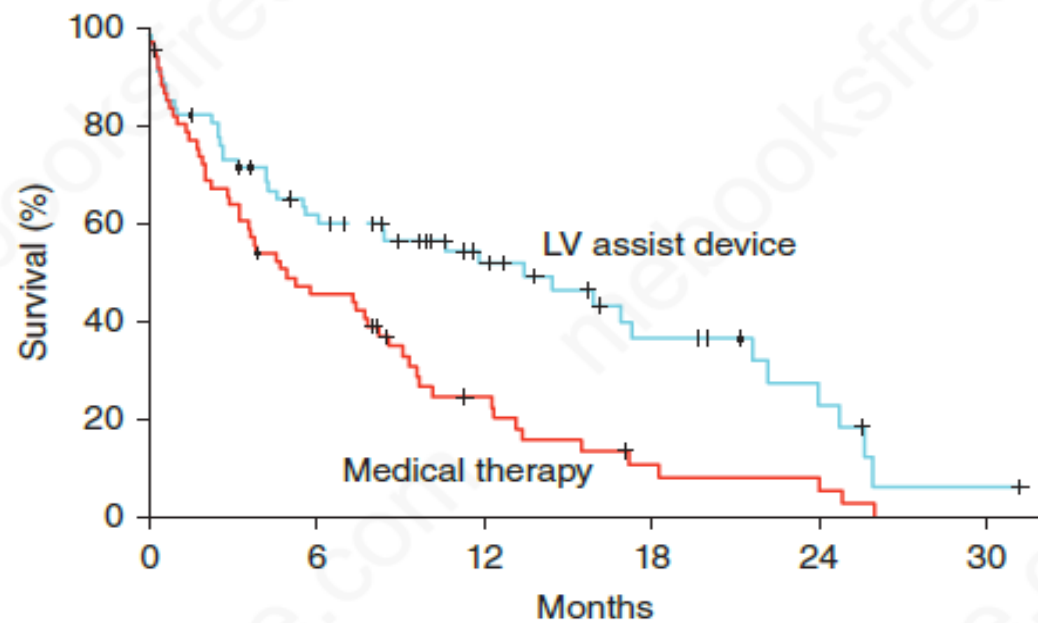
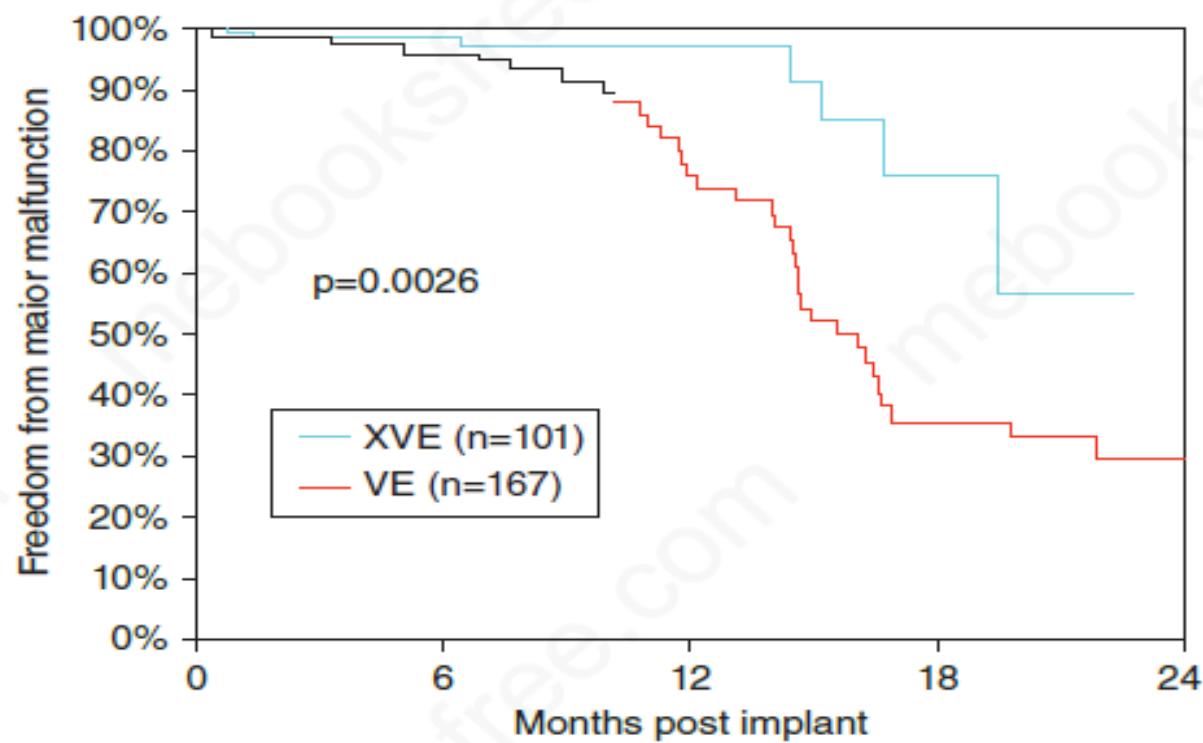


FIGURE 62-3 The Jarvik 2000 was the first left ventricular assist device to incorporate blood-washed bearings in its axial flow design. (Used with permission from Jarvik Heart, Inc.)



No. at risk						
LV assist device	68	38	22	11	5	1
Medical therapy	61	27	11	4	3	0

FIGURE 62-4 Kaplan-Meier survival analysis comparing end-stage heart failure patients randomized to receive either optimal medical therapy or left ventricular assist device support. The REMATCH trial researchers demonstrated a significant survival benefit for device recipients at both 1 and 2 years. (Reproduced with permission from Rose EA, Gelijns AC, Moskowitz AJ, et al: Long-term use of a left ventricular assist device for end-stage heart failure, *N Engl J Med.* 2001 Nov 15;345(20):1435-1443.)



Time	0	1 month	6 months	12 months	18 months
VE patients at risk	167	133	77	37	14
XVE patients at risk	101	84	59	29	4

FIGURE 62-5 Freedom from all major device malfunctions for the HeartMate VE and HeartMate XVE left ventricular assist devices. (Reproduced with permission from Pagani et al. Improved mechanical reliability of the HeartMate XVE Left Ventricular Assist System, *Ann Thorac Surg.* 2006 Oct;82(4):1413-1418.)

***PULSATILE VERSUS
NONPULSATILE
FLOW***

**TABLE 62-2: Currently Available Options for Mechanical Circulatory Support**

Device	Manufacturer	Flow type	Design	First human implant	Approval status	
<i>Paracorporeal</i>					<i>Worldwide</i>	<i>United States</i>
CentriMag®	Thoratec Corp. (Pleasanton, CA)	Continuous	Centrifugal	2003	CE Mark—2002	FDA 510(k)—2002 FDA IDE—2008 FDA HDE RVAD—2008
<i>Percutaneous</i>						
Impella 5.0®/CP®/RP®	ABIOMED	Continuous	Microaxial	1999	CE Mark 5.0—2003 CP—2012 RP—2014	FDA 510(k) 5.0—2009 CP—2012 FDA HDE RP—2015
TandemHeart™	CardiacAssist, Inc. (Pittsburgh, PA)	Continuous	Centrifugal	2005	CE Mark—2000	FDA 510(k)—2003 FDA IDE—2012
<i>Implantable LVADs</i>						
HeartMate® II	Thoratec	Continuous	Axial	2000	CE Mark—2005	FDA BTT—2008 FDA DT—2010
Jarvik 2000 Flowmaker®	Jarvik Heart, Inc. (New York, NY)	Continuous	Axial	2000	CE Mark—2005	FDA IDE—2000 BTT Trial Pending
INCOR®	Berlin Heart GmbH (Berlin, Germany)	Continuous	Axial	2002	CE Mark—2003	—
EVAHEART®	Evaheart, Inc. (Houston, TX)	Continuous	Centrifugal	2005	CE Mark—2015 PMDA—2010	FDA IDE—2009 BTT Trial Pending
HVAD®	HeartWare, Inc. (Framingham, MA)	Continuous	Centrifugal	2006	CE Mark—2009	FDA BTT—2012 DT Trial Pending
HeartAssist 5®	ReliantHeart, Inc. (Houston, TX)	Continuous	Axial	2009	CE Mark—2013	FDA IDE—2014 BTT Trial Pending
HeartMate® III	Thoratec	Continuous	Centrifugal	2014	CE Mark Pending	FDA IDE—2014 BTT/DT trial pending
MVAD®	HeartWare	Continuous	Axial	2015	CE Mark Pending	Awaiting FDA IDE
<i>Total Artificial Heart</i>						
SynCardia TAH	SynCardia Systems, Inc. (Tucson, AZ)	Pulsatile	Pneumatic	1982	CE Mark—1999	FDA HDE—2004

CE Mark, European Union Conformité Européenne Approval; FDA, United States Food and Drug Administration; 510(k), Premarket Notification Clearance; PMA, premarket approval; IDE, investigational device exemption; HDE, humanitarian device exemption; BTT, bridge to transplant; DT, destination therapy; PMDA, Japanese Pharmaceuticals and Medical Devices Agency Approval; TAH, total artificial heart.

***Implantable Continuous-
Flow LVADs
(FDA-Approved)***

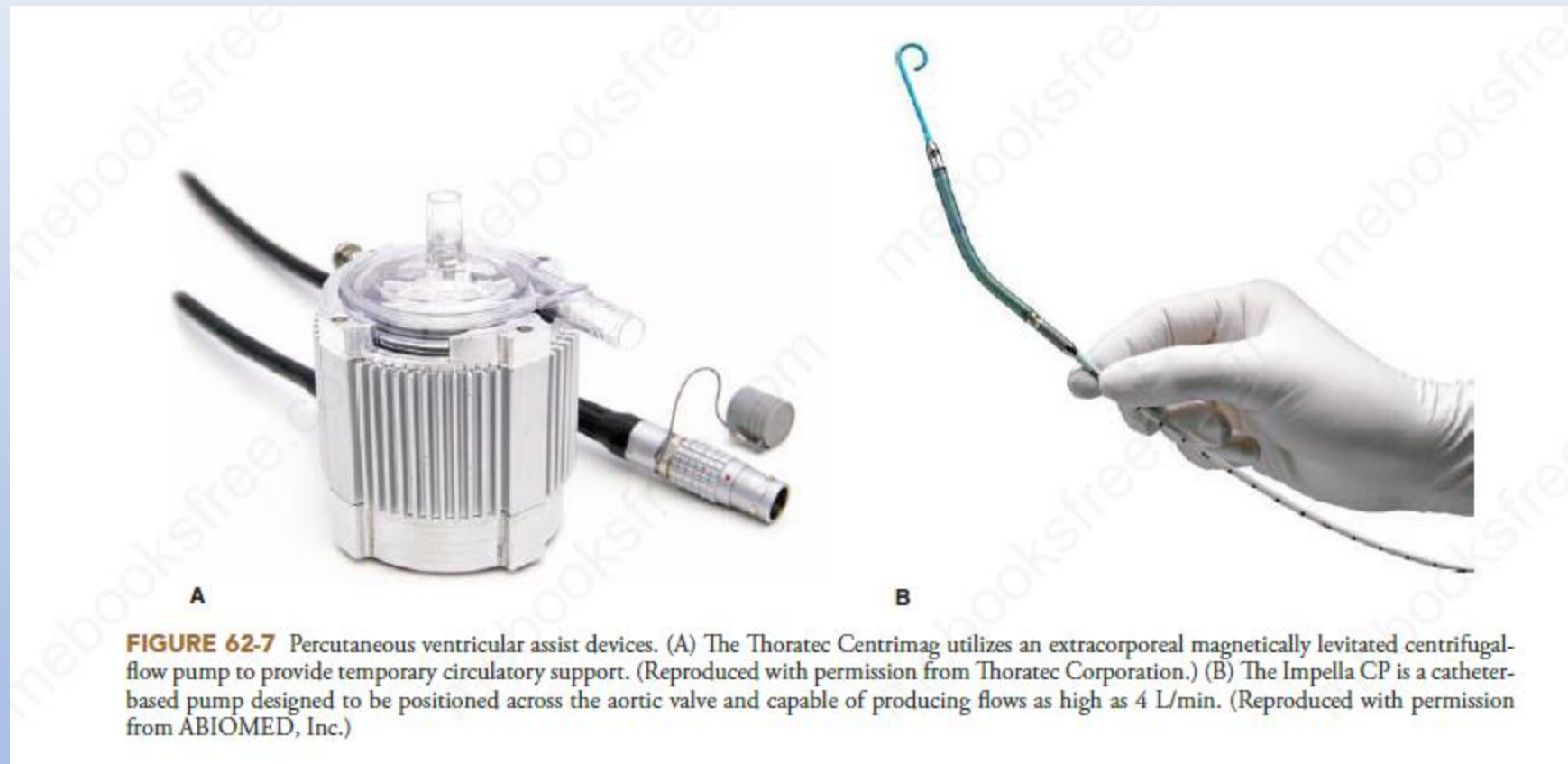




FIGURE 62-8 The HeartMate II (A) and the HeartWare HVAD (B) are the two most commonly implanted devices worldwide. While the HeartMate II utilizes an axial-flow design with an extracardiac pump housing, the centrifugal HVAD has a discoid shape designed for intrapericardial placement. Newer-generation devices, such as the HeartWare MVAD (C), reflect increasing miniaturization of mechanical circulatory support technology. (Used with permission from Thoratec Corporation [a] and HeartWare International, Inc. [b and c].)

***GOALS
OF
THERAPY***

Bridge to Transplantation

Bridge to Decision

Myocardial Reconditioning

Destination Therapy

Fluidity of Implantation Strategy

 **TABLE 62-3: Comparison of ACCF/AHA Stages of HF and NYHA Functional Classifications**

ACCF/AHA HF stages		NYHA functional classification	
A	At high risk for HF but without structural heart disease or symptoms of HF	I	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF
B	Structural heart disease but without signs or symptoms of HF	II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF
C	Structural heart disease with prior or current symptoms of HF	III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF
D	Refractory HF requiring specialized interventions	IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest

ACCF, American College of Cardiology Foundation; AHA, American Heart Association; NYHA, New York Heart Association; HF, heart failure. Reproduced with permission from Yancy CW, Jessup M, Bozkurt B, et al: 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines, *Circulation*. 2013 Oct 15;128(16):e240-e327.

***CONTRAINDICATIONS
TO
DEVICE SUPPORT***

CONTRAINDICATIONS

- IRREVERSIBLE MAJOR ENDORGAN DYSFUNCTION
- SEVERE HEMODYNAMIC
- PROFOUND COAGULOPATHY
- COMPLEX CONGENITAL DIS,
- RESTRICTIVE HEART DIS,
- ACTIVE INFECTION

- DECISION MADE ON CASE BY CASE



TABLE 62-5: Multivariable Predictors of 90-Day Mortality (HeartMate II Risk Score)

Parameter	SE	OR (95% CI)	p Value
Age (years)	0.12	1.32 (1.05-1.65)	.018
Albumin (g/dL)	0.23	0.49 (0.31-0.76)	.002
Creatinine (mg/dL)	0.20	2.10 (1.37-3.21)	<.001
INR	0.32	3.11 (1.66-5.84)	<.001
Center volume	0.34	2.24 (1.15-4.37)	.018
	Low risk	Medium risk	High risk
HMRS score	<1.58	1.58-2.48	>2.48
90-Day survival	96% (± 1%)	84% (± 2%)	71% (± 4%)

HMRS = $(0.0274 \times \text{Age}) - (0.723 \times \text{Alb}) + (0.74 \times \text{Creat}) + (1.136 \times \text{INR}) + (0.807 \times \text{Vol})$.

*Center Volume: Yearly LVAD implant volume <15, value = "0";
Yearly volume >15, value = "1".

SE, standard error; OR, odds ratio; CI, confidence interval; INR, international normalized ratio; HMRS, HeartMate II Risk Score; Alb, albumin; Creat, creatinine; Vol, yearly device implant volume; LVAD, left ventricular assist device.

Adapted with permission from Cowger J1, Sundareswaran K, Rogers JG, et al: Predicting Survival in Patients Receiving Continuous Flow Left Ventricular Assist Devices: The HeartMate II Risk Score, *J Am Coll Cardiol*. 2013 Jan 22; 61(3):313-321.

End-Organ Function

Operative Risk

Right Ventricular Function

Multidisciplinary

Assessment

/

Social Evaluation

DEVICE SELECTION



Live Case



iVAC 2L Procedure

A. Clinical benefits:

- a. Ivac 2L is pulsatile synchronize LV support this is more natural than continuance flow. The optimum Oxygen perfusion to tissue cells needs the diastolic phase.
- b. Due to Synchronization and pulsatile the Ivac 2L reduce after load pressure in aorta during systole therefore LV needs less pressure/energy to move from diastole to systole.
- c. Ivac 2L takes the remaining blood from LV during systole without overtaking LV CO.
- d. Ivac 2L increase volume during diastole phase and therefore increase diastolic pressure up to 50%.
- e. Ivac 2L is “net” support up to 2 L/m on top LV CO (a+b). Impella generate fixed volume and overtake some of systolic volume generated by LV so in average the additional volume of Impella CP is very similar to Ivac 2L .
- f. Hemolysis level of Ivac 2L is very low less than 10mg/dL of free hemoglobin , Impella generate between 50-100mg/dL , Quality of blood with Ivac 2L is much better.

B. Technical advantages:

- a. Very simple and basic procedure, placing catheter tip in LV is a daily routine for these doctors.
- b. Using standard IAB driver that exists in every cathlab, the Ivac 2L can work with Maquet or Arrow devices.
- c. Simple device preparation (flushing).
- d. The device build with simple mechanical valve and membrane pump without electronics, sophisticated motors and pumps or complicated consoles.
- e. Very short learning curve – 2-3 cases
- f. Very stable position almost no movement during pumping – Impella creates vibration and tip migrant due to 60K RPM blood pump.

C. Commercial advantages:

- a. Price – Ivac 2L got a very attractive price comparing Impella 8K Vs 13K
- b. No need to buy special console with cost of 35K – they can use existing IAB drivers
- c. All in one kit – all insertion kit pump and catheter are including in Ivac 2L kit.



HeartMate 3TM LVAS

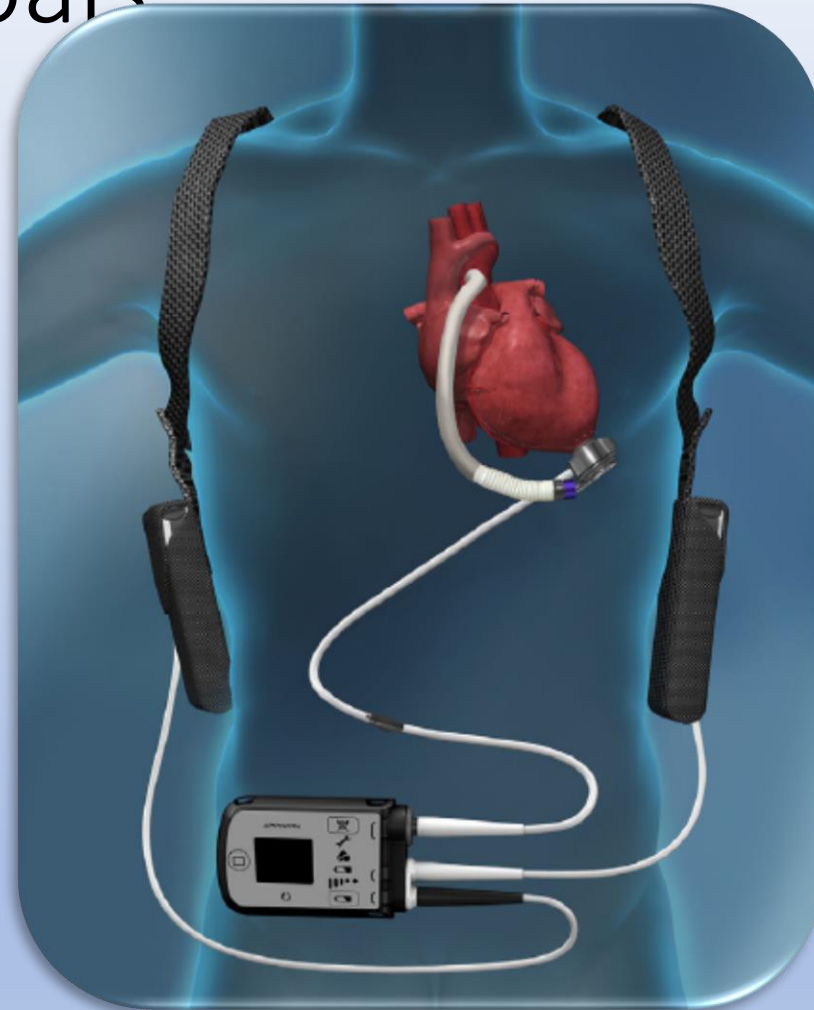
Clinical Operation and
Patient Management





HeartMate 3: Design Goals

- Build upon the highly successful HeartMate II LVAS
- Enhanced AE profile
- Increased surgical ease
- Elevate the patient experience



A Healthy Respect for Blood

What influences Hemocompatibility?

- Designed for Hemocompatibility
 - Minimizes shear stress
 - Minimize stasis
 - Minimize activation of blood components
 - Minimize interactions between the blood and the contacting surfaces

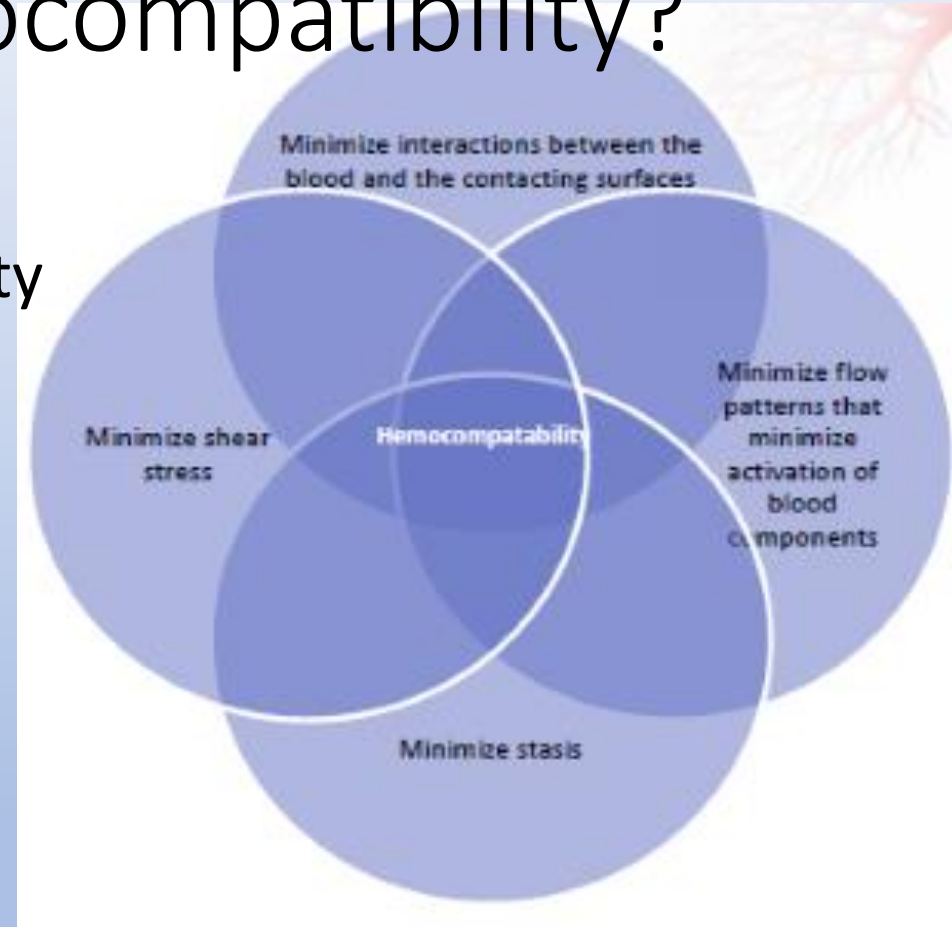


FIGURE 62-9 HeartMate II implantation.

(A) Retraction of the diaphragm in anticipation of subdiaphragmatic pump positioning.

(B) The ventricle is cored along the diaphragmatic surface of the heart—lateral to the posterior descending artery—and a plegeted ring secures the Silastic inflow cuff.

(C) Transdiaphragmatic positioning of the HeartMate II inflow cannula.

(D) Anastomosis of the outflow graft to the ascending aorta, aided by a partial occluding vascular clamp.

(E) Final alignment of the pump and outflow conduit. The pump housing lies beneath the diaphragm, and the outflow graft courses toward the right side of the chest. Introduction of a 19-gauge needle permits de-airing of the system.

***POSTOPERATIVE
MANAGEMENT***

Anticoagulation

POSTOPERATIVE OUTCOMES

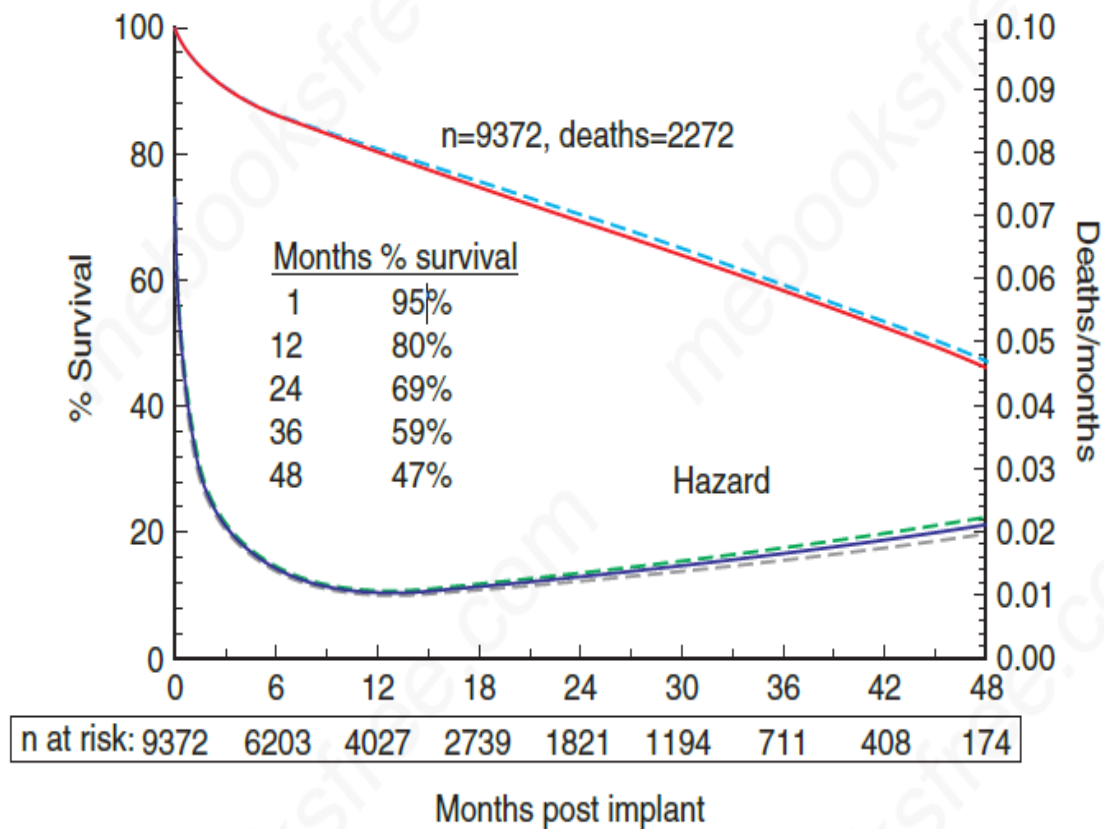


FIGURE 62-10 Actuarial survival curve for adult recipients of primary continuous-flow left ventricular support. Patients were censored at transplantation or device explantation. (Reproduced with permission from Kirklin JK, Naftel DC, Pagani FD, et al: Sixth INTERMACS annual report: a 10,000-patient database, *J Heart Lung Transplant*. 2014 Jun;33(6):555-564.)

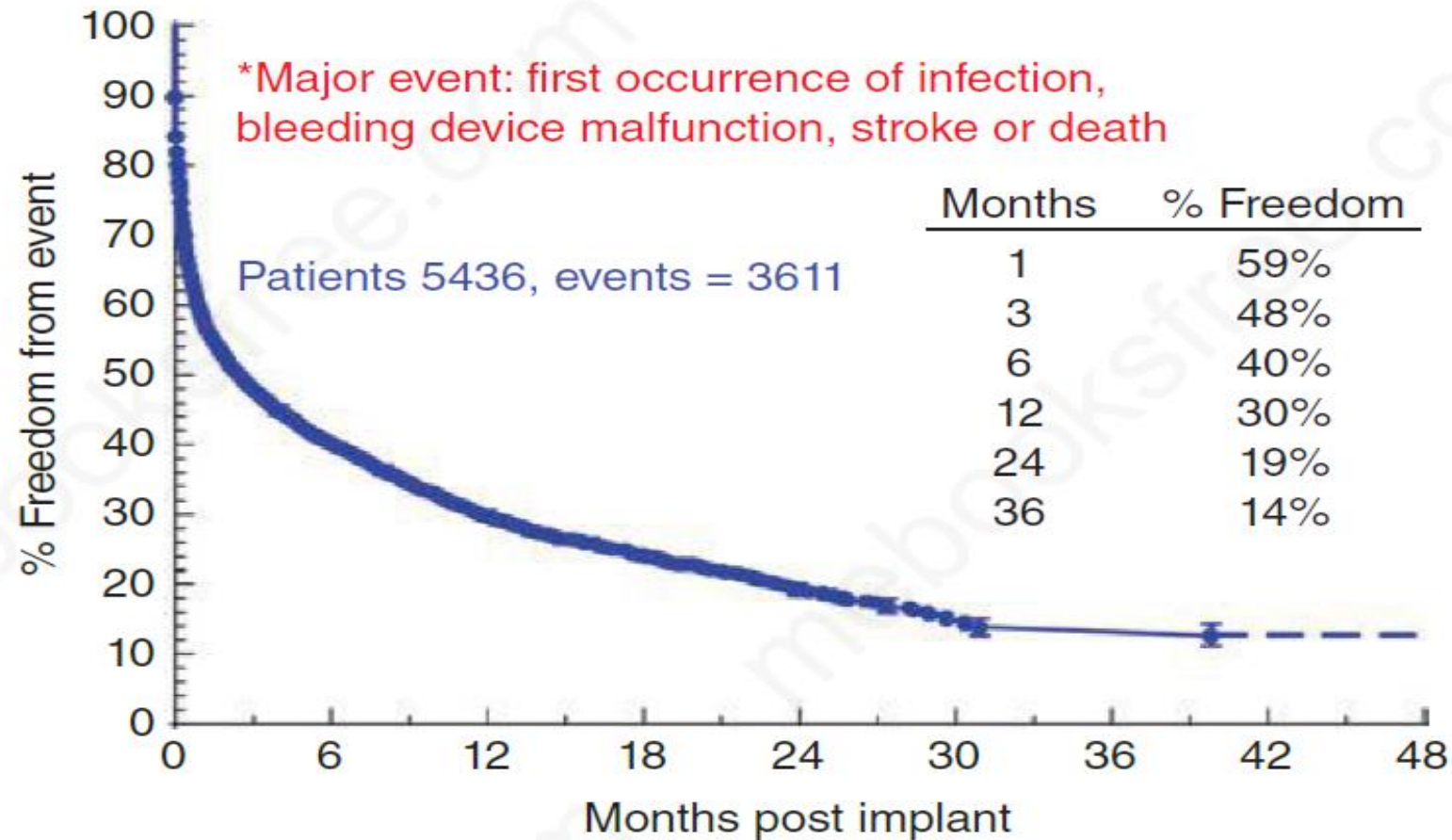


FIGURE 62-11 Actuarial freedom from major adverse events in patients supported by continuous-flow left ventricular assist devices. (Reproduced with permission from Kirklin JK, Naftel DC, Kormos RL, et al: Fifth INTERMACS annual report: risk factor analysis from more than 6,000 mechanical circulatory support patients, *J Heart Lung Transplant*. 2013 Feb;32(2):141-156.)

ADVERSE EVENTS AND DEVICE COMPLICATIONS

Perioperative Bleeding

Right-Sided Heart Failure

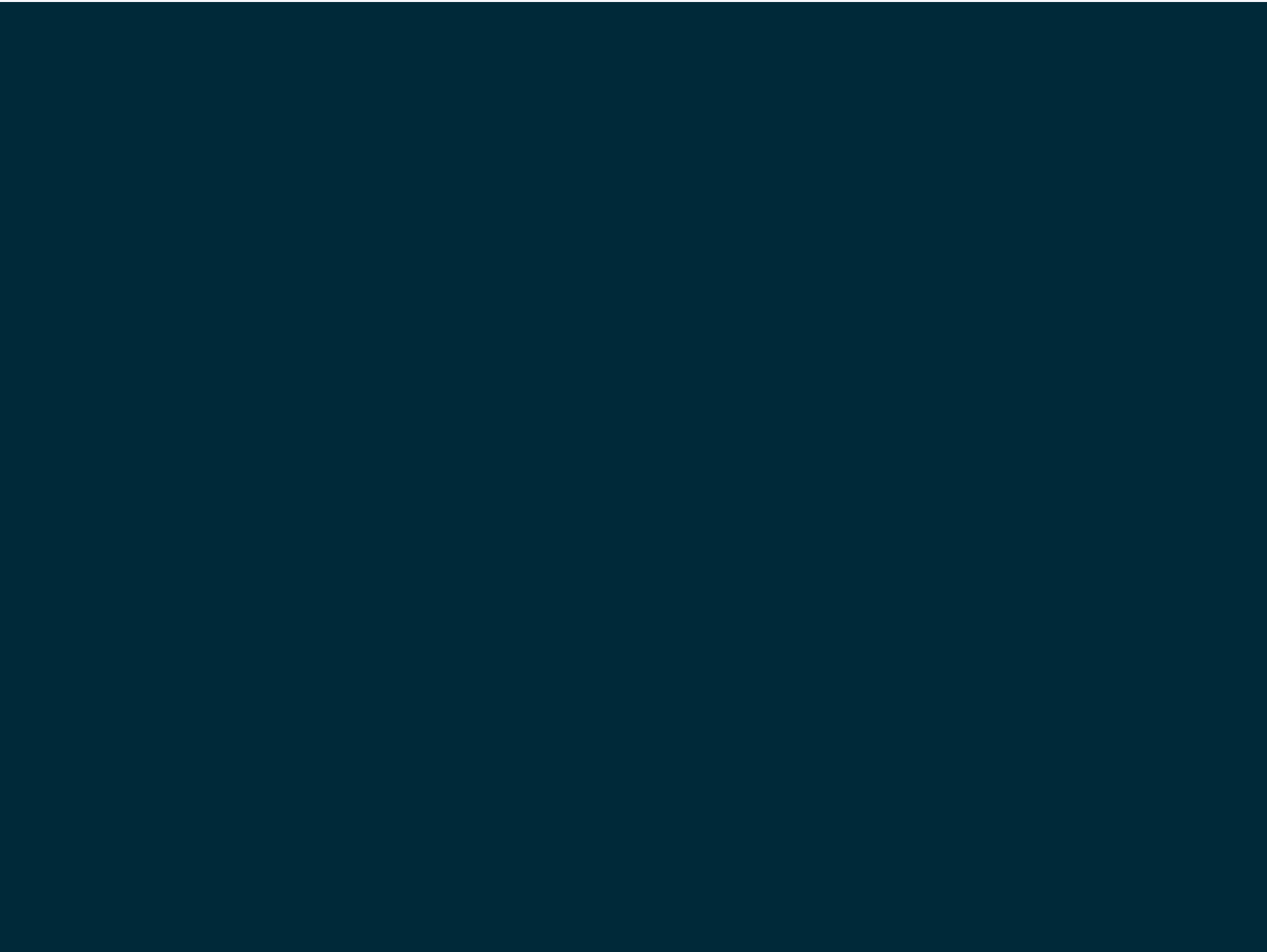
Infection

Renal Failure

Stroke and Neurologic Dysfunction

Nonsurgical and Gastrointestinal Bleeding

Pump Thrombosis and Device Malfunction



HeartMate 3

***Designed to be Hemocompatible
Leveraging Full MagLev™ Technology***



Features

- **Full MagLev**
 - Large, consistent pump gaps designed to reduce blood trauma
 - Artificial pulse
 - Wide range of operation
 - Full support (2.5 – 10 L/min)
- Textured blood contacting surfaces
- Advanced Design for Surgical Ease
 - Engineered apical attachment
 - Modular Driveline
- Designed for an Active Lifestyle
 - System Controller



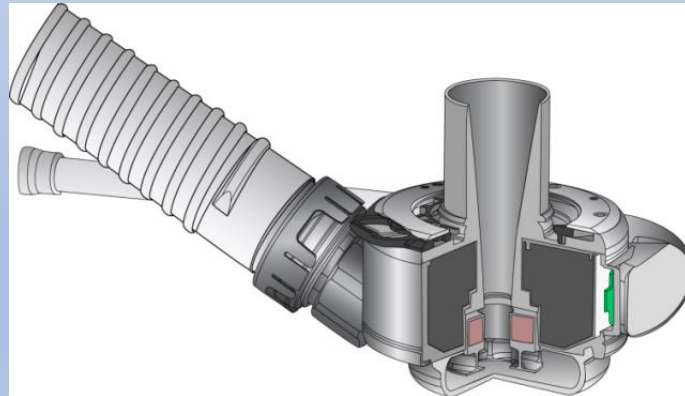
HeartMate 3 LVAD



HeartMate 3™*: Full MagLev Technology

Key Design Feature: Wide Range of Operation

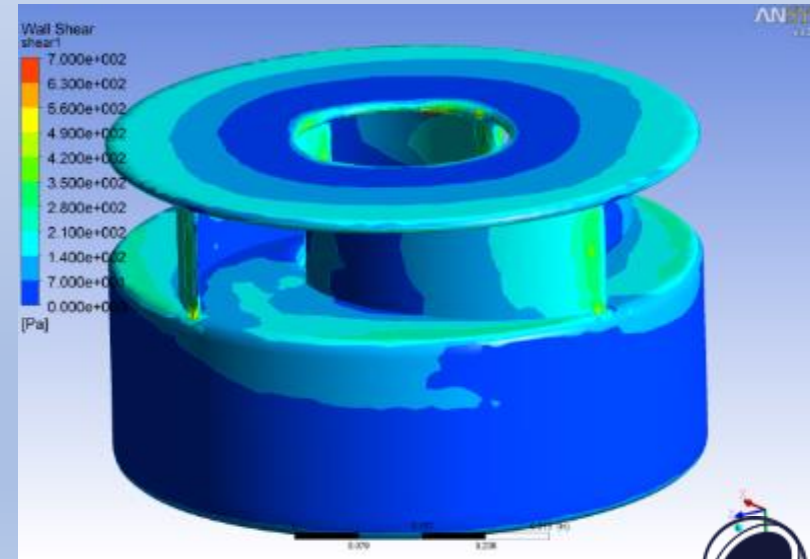
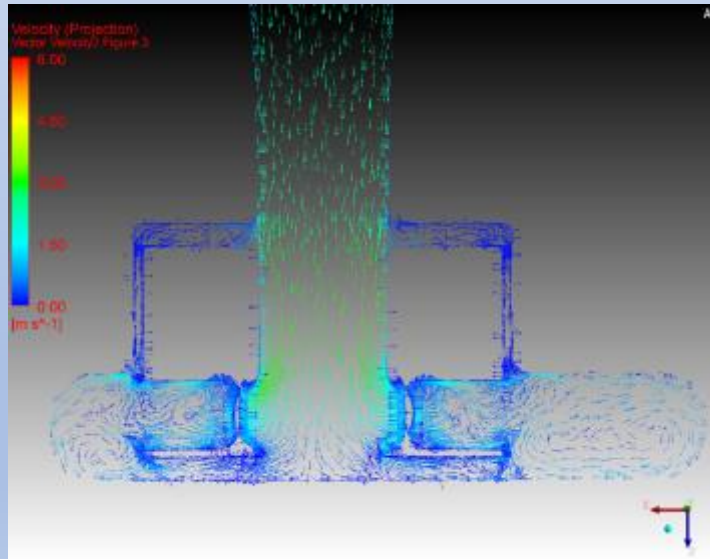
- **HeartMate 3 rotor levitation is independent of rotor speed**; levitation is maintained at any rotor speed, even zero.
 - Conversely, for a hydrodynamic bearing the rotor scrapes the housing surface until it comes up to speed and entrains a thin layer of blood to produce lift; a certain critical speed must be maintained to avoid rotor/housing contact.
- **Rotor speed independence permits flexibility in operating speeds**, which could in the future enable use in low-speed conditions, e.g., pulmonary circulation, weaning protocols, etc.



HeartMate 3: Full MagLev Technology

Key Design Feature: Fluid Dynamics (Designed to Minimize Shear Stress and Activation of Blood Components)

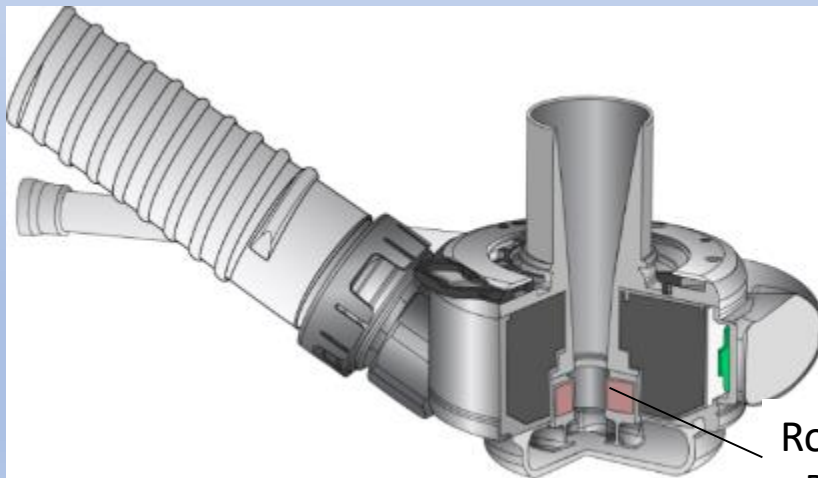
- The HeartMate 3 rotor and inlet have been designed to minimize shear and avoid stasis over the entire range of operation (2.5 to 10 L/min).
- The relatively large secondary flow paths facilitate smooth flow transitions, generous washing, and low shear.



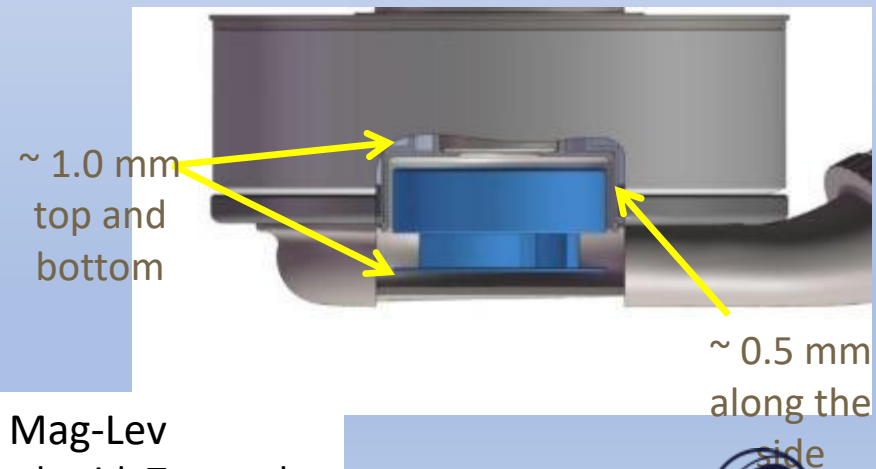
HeartMate 3™. Full MagLev Technology

Key Design Features: Large and Consistent Gaps (Designed to minimize Shear Stress and Blood Component Activation)

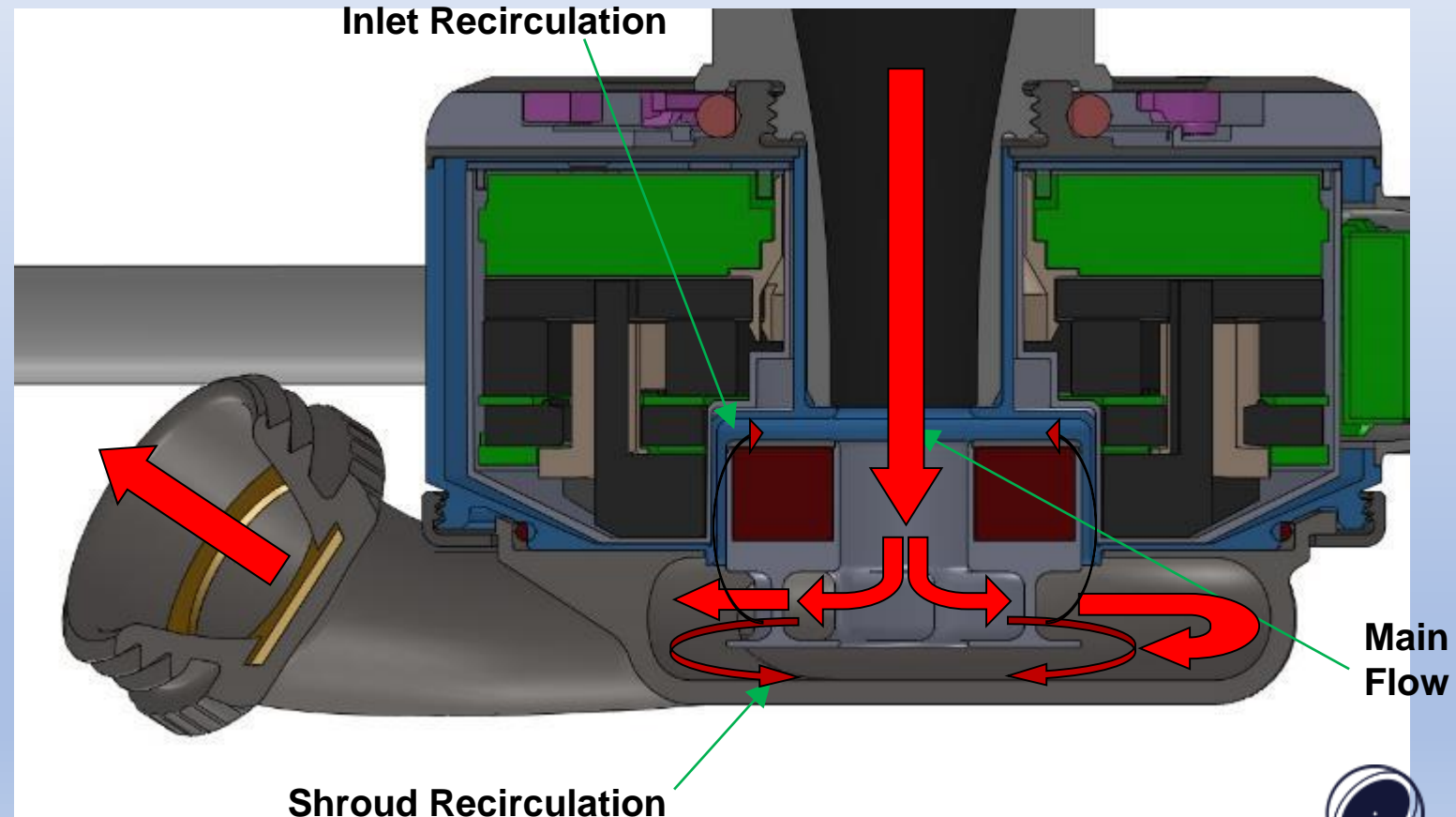
- HeartMate 3 secondary flow paths are **~0.5 mm** along the side, and **~1.0 mm** above and below the rotor
 - Conversely, hydrodynamic bearings are typically operated with much smaller gaps, roughly **0.05 mm**
- HeartMate 3 pump surfaces are flat and flow is undisturbed
 - Wedging surfaces and other features required for hydrodynamic bearings are not required



Rotor & Mag-Lev
- Blood path with Textured Surfaces



HeartMate 3™: Full MagLev Technology



How much difference is there?⁶⁷

From a Red Blood Cell's Point of View



6-8 μm

	Gap Size	# of Red Blood Cells
Full MagLev	1,000 μm	167
Hydrodynamic Bearing	50 μm	8

8

Stacked RBCs

at least
20X larger
blood flow
paths



HeartMate 3™ LVAS Surgical Implantation

Surgical Implant

- General Warnings and Cautions
- Pump Cable Placement
- Aortic Anastomosis
- Apical Anastomosis
- De-Airing & Hemostasis
- Closing
- Explantation

00:00:00:00

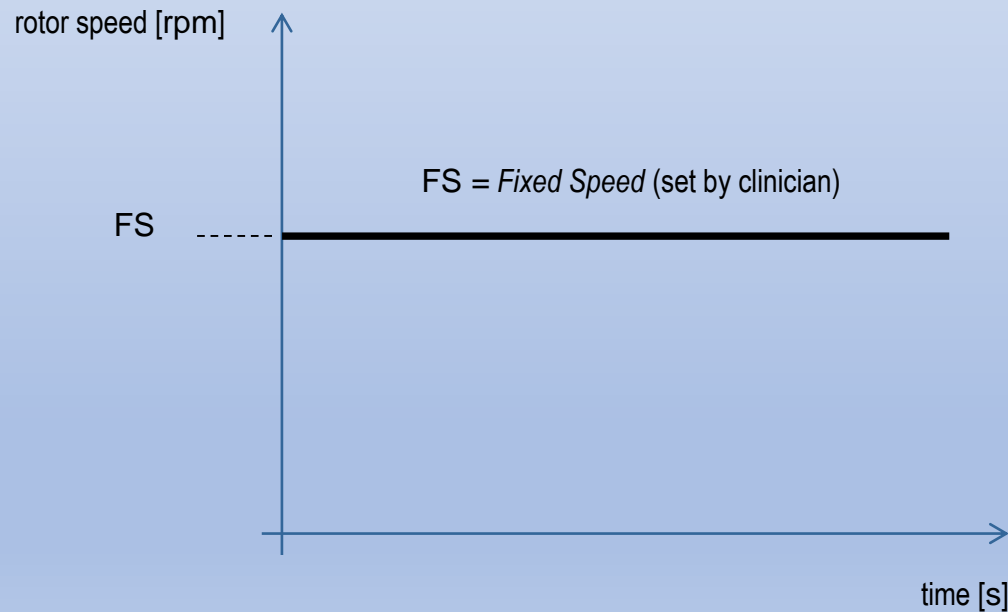
HEARTMATE 3™ LVAD WITH FULL MAGLEV™ FLOW TECHNOLOGY



See Important Safety Information referenced within.

LVAD Operating Modes

- Fixed Speed Mode
 - Pump speed does not change
 - Operating mode when fixed speed set < 4000 rpm, No External Power alarm, or Low Power Hazard alarm



HeartMate 3™*: Pulsatility

Key Design Feature: Pulsatility (Minimize stasis)

- The large gaps also enable the rapid speed changes used by our artificial pulse feature without rotor/housing contact.

Some potential benefits:

Designed to promote washing of the pump

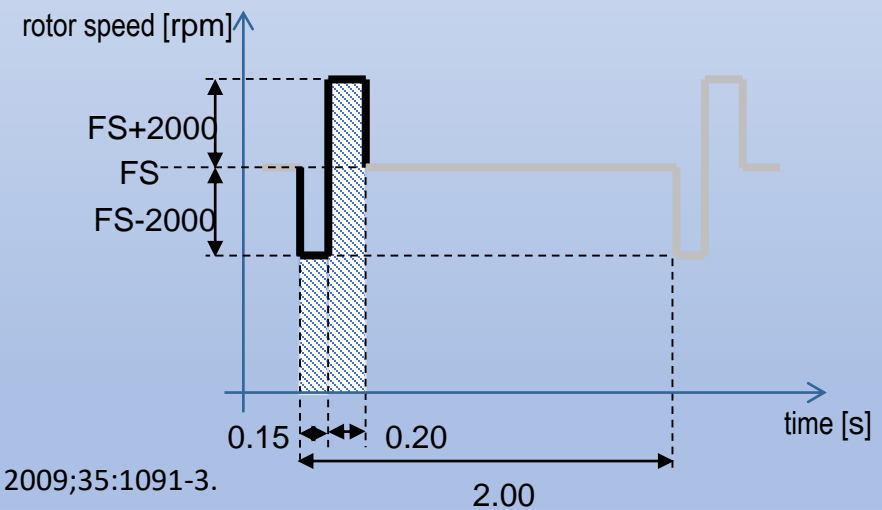
- Prevents the formation of zones of recirculation and stasis.

Zero Net Change in Flow

- Speed ramps up and down (zero net change)

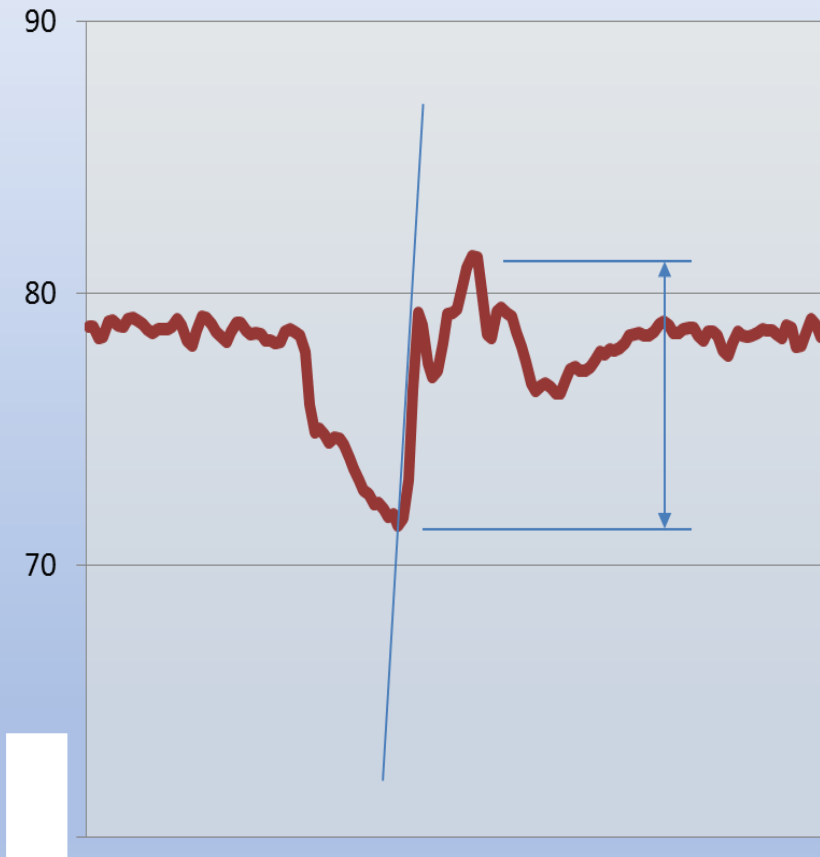
Potential Clinical Benefits¹⁻³

1. Tsai H. S., et al. *Semin Thromb Hemost* 2003;29(5):479-88.
2. Malehsa D, Meyer AL, Bara C, Struber M. *Eur J Cardiothorac Surg* 2009;35:1091-3.
3. Crow S, et al *J Thorac Cardiovasc Surg* 2009;137:208-15.



HeartMate 3™: Artificial Pulse

Carotid Pressure Head,
[mmHg]



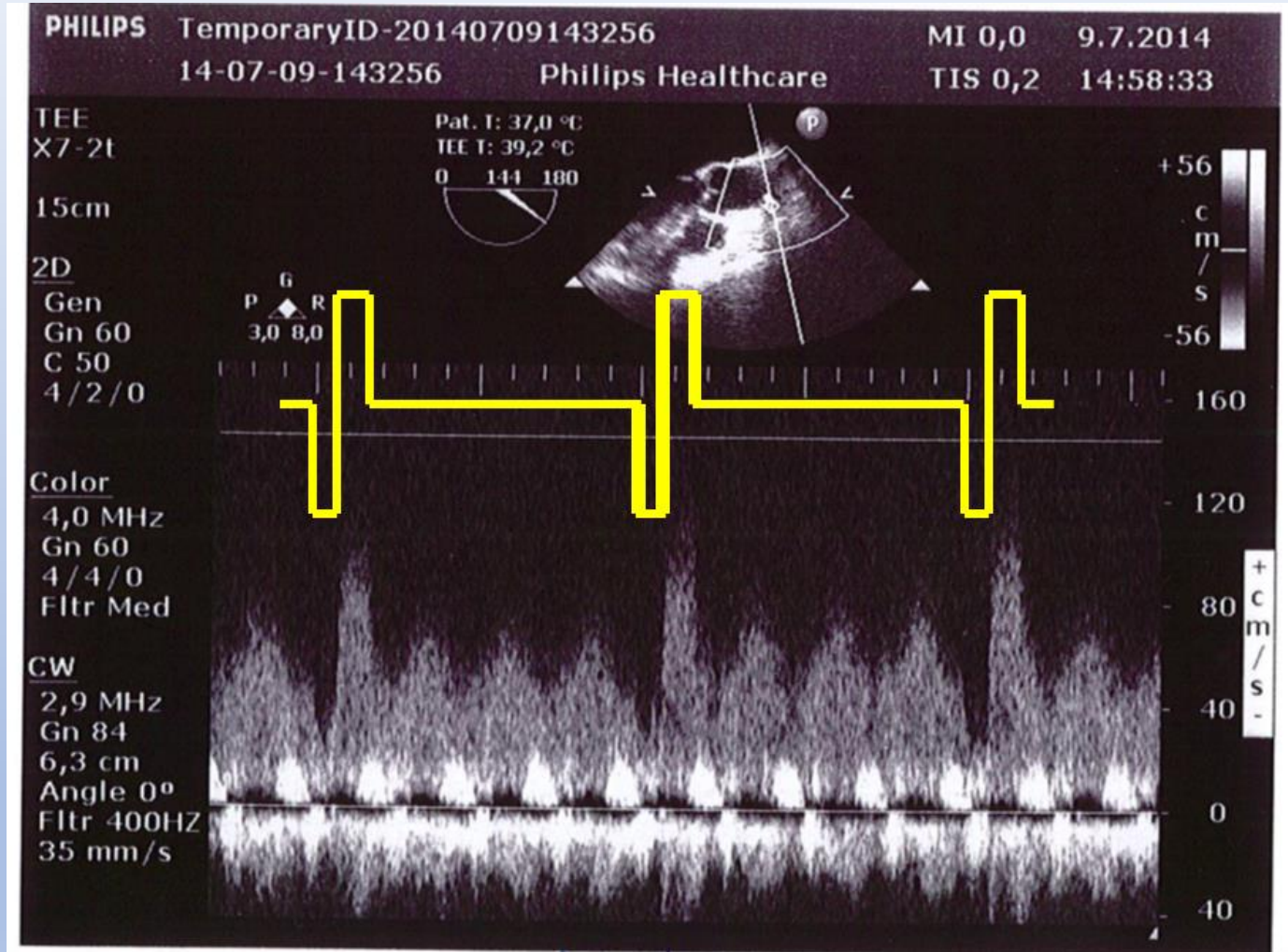
- From *in vivo* data, the incremental power consumption of the pulse mode is approximately 5%¹

t_d [s], t_k [s]	Pulse Pressure [mmHg] (n=14)	$\delta P/\delta t$ [mmHg/s] (n=14)	Surplus Hemodynamic Energy [ergs/cm ³] (data set)
0.20, 0.15	10.17 ± 0.38	335.3 ± 20.6	244

¹ 2012 ISRBP Conference presentation: *In Vivo* Evaluation of LVAD Artificial Pulse Parameters and Synchrony with the Native Heart, K. Bourque, C. Cotter, C. Dague, K. Handy, M. Sobieski, S. Koenig, M.S. Slaughter, S. Parnis, W. Cohn, O.H. Frazier



HeartMate 3™: Artificial Pulse



HeartMate 3™ Electronics



- HeartMate III control electronics are located inside the implanted pump
- HeartMate III pump parameters and settings are stored in the pump
 - This eliminates setting the speed in the patient's backup System Controller
 - The pump will run at the most recent settings (even if communication between the pump and System Controller is interrupted)
- HeartMate III has software in the pump *and* Controller
 - Both the Pump and System Controller have their own log files (periodic and event)



HeartMate 3 is Different from the HeartMate II.....



- HeartMate 3 driveline comprised of two cables
 - Pump cable permanently attached to the pump and tunneled through the skin
 - Modular cable attaches to the pump cable and connects to the controller
- HeartMate 3 control electronics are located inside the implanted pump
- HeartMate 3 pump parameters and settings are stored in the pump
 - This eliminates setting the speed in the patient's backup System Controller
 - The pump will run at the most recent settings (even if communication between the pump and System Controller is interrupted)
- HeartMate 3 has software in the pump *and* Controller
 - Both the Pump and System Controller have their own log files (periodic and event)
- HeartMate 3 pump operates with an artificial pulse
 - Activates every 2 seconds (30 per minute)



Key Verifications

- Verify Cable immobilization
- Verify EBB installation
- Do not clamp the OGBR
- No anatomical or surgical elements that could cause wear or abrasion

Explantation

Device Explant

- Dissection & Exposure
- Discontinue LVAD support
 - Disconnect Driveline from System Controller
- Clamp Outflow Graft
- Open Cuff Lock & remove LVAD
- Cut Driveline & externalize LVAD
- Close Aortic track
- Close

TOTAL ARTIFICIAL HEART

Early Development and Experience

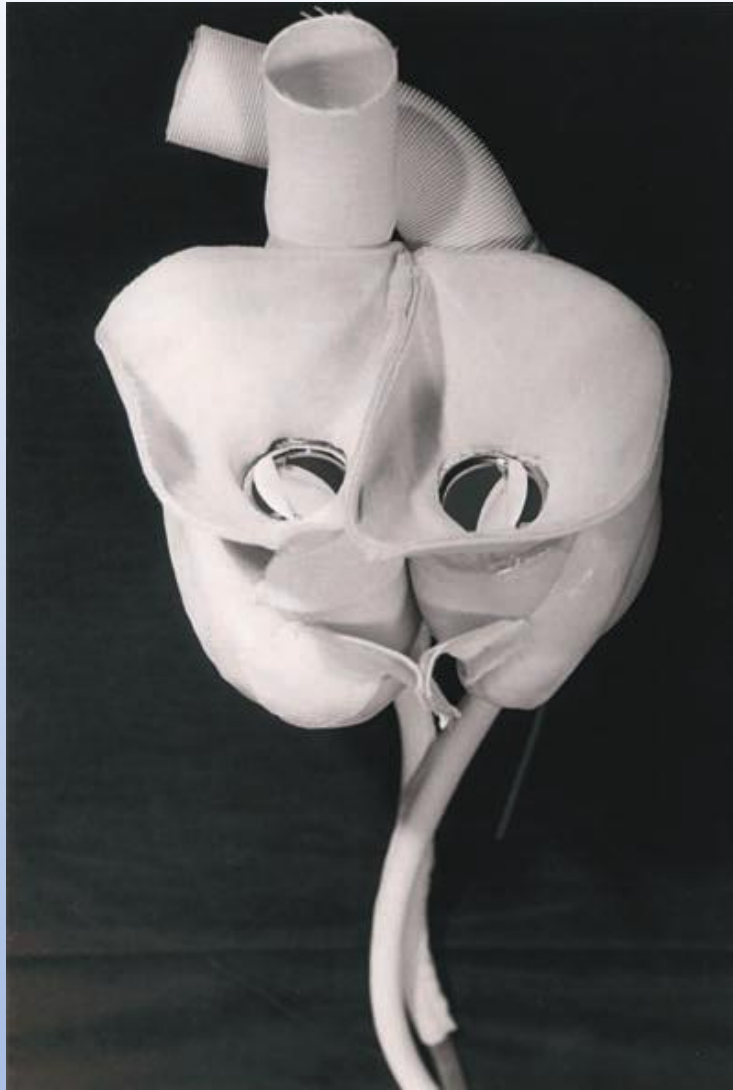


FIGURE 62-12 The Liotta total artificial heart, the first to be implanted in a human. (Courtesy Texas Heart Institute.)



FIGURE 62-13 The Syncardia Total Artificial Heart (formerly the Jarvik-7, Symbion, and CardioWest TAH) utilizes two pneumatically driven pumps for biventricular support. (Courtesy: SynCardia Systems, Inc.)

Contemporary Options for Total Heart Replacement

SYNCARDIA TAH



FIGURE 62-14 The AbioCor Implantable Replacement Heart.
(Reproduced with permission from ABIOMED, Inc.)

Complexities of Mechanical Total Heart Replacement

Future Directions: the CF TAH



FIGURE 62-15 The BiVACOR total artificial heart employs a single moving part—a central magnetically levitated rotor—to provide complete cardiopulmonary support. (Reproduced, with permission, from BiVACOR, Inc.)

KEY POINTS

A photograph of a misty forest path. The path is a narrow, winding trail of dark brown earth, flanked by lush green ferns and other forest vegetation. Tall, slender trees stand in the background, their trunks partially obscured by a soft, white mist. The overall atmosphere is serene and quiet. A red text overlay is positioned diagonally across the upper middle of the image.

•THANK YOU FOR YOUR ATTENTION