

Live Case #1: VR, 85 yrs old M

Presentation: Exertional angina & dyspnea on walking ½ block for 2 mths

Positive stress MPS for significant inferior and anterior ischemia and partial infarction

Past History: Hypertension, Hyperlipidemia, Ex-Smoker, CRI, PVD

Medications: ASA, Plavix, Lipitor, Lisinopril, HCTZ, Mucomyst

Cardiac Cath: 06/30/09:

2 Vessel CAD and LVEF 25%

Left Main: No obstruction

LAD: proxLAD 50%, calcified complex midLAD 95%
/ Diag 70% bifurcation lesion

LCx: Non-obstructive

RCA: mid 90% and distal 95% calcific lesions

Prior PCI: PCI of RCA (Xience V in mid and PTCA of distal lesion)

Plan Today: Intervention of LAD/Diag with LV assist Device

Live Case #1: Important Procedural Issues

ISSUES:

- **Anticoagulation: DTI vs. Heparin+ GPI, DTI+GPI**
- **Lesion Complexity: Calcification, Bifurcation**
- **Plaque Modification: Rotational Atherectomy, CB, NCB**
- **LV Support: IABP, Impella or PTVA**

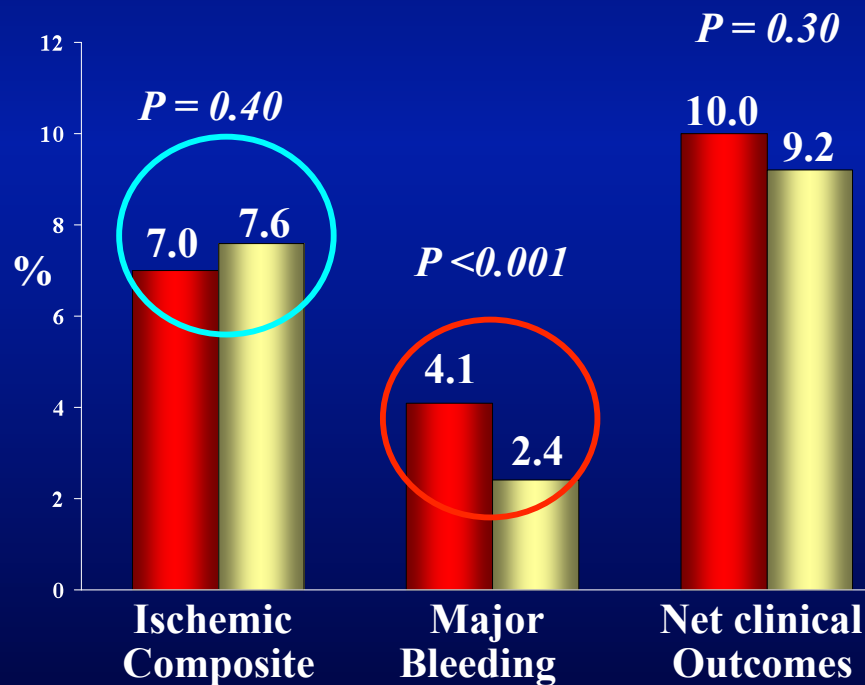
REPLACE-2 vs. ACUITY PCI: 30-Day Events

REPLACE-2 PCI

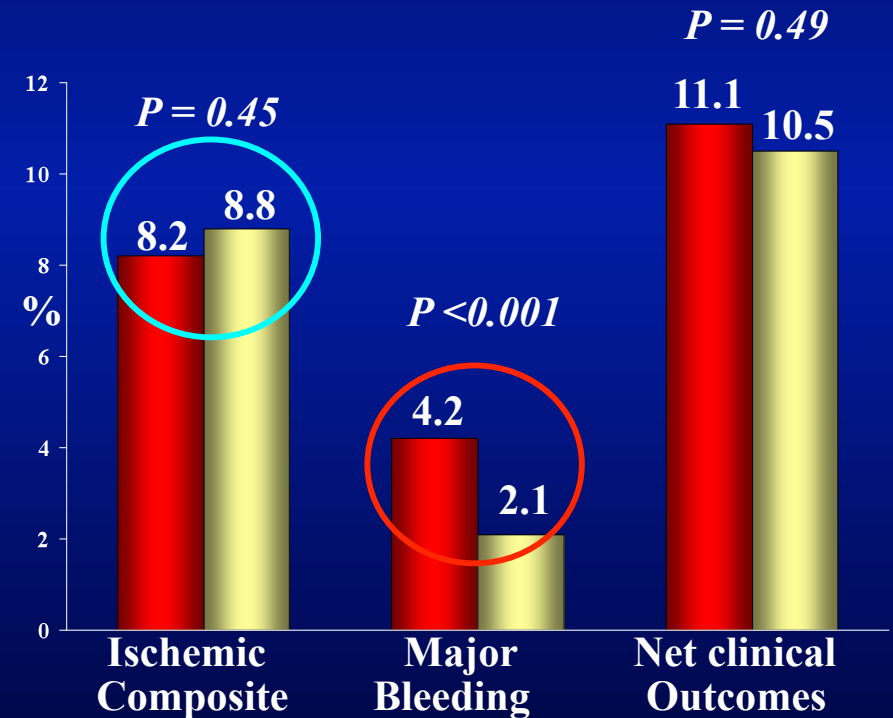
ACUITY PCI

■ Heparin + GP IIb/IIIa (n = 3008)
■ Bivalirudin alone (n = 2994)

■ Heparin + GP IIb/IIIa (n = 2619)
■ Bivalirudin alone (n = 2561)



Lincoff et al. JAMA 2003;289:853



Stone et al, N Engl J Med 2006;355:2203

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Impact of Lesion Calcium on Stent (BMS) Expansion (OSTI Trial)

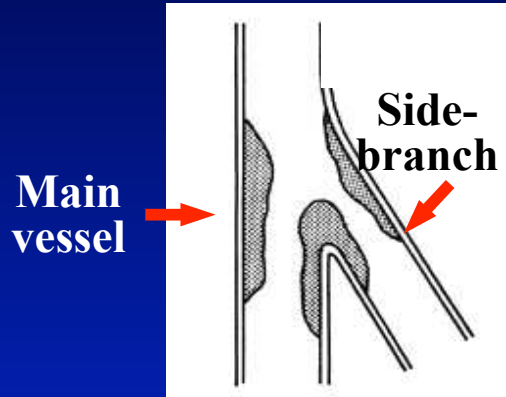
Predictors of Stent Expansion

	12 atm	15 atm	18 atm
Ca⁺⁺ (n=15)	66%	69%	71%
Non Ca⁺⁺ (n=25)	82%	93%	100%

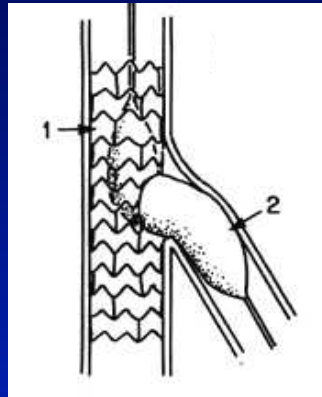
Stone et al. AJC 1999;83:1397

Various Techniques for Stenting Bifurcation Lesions

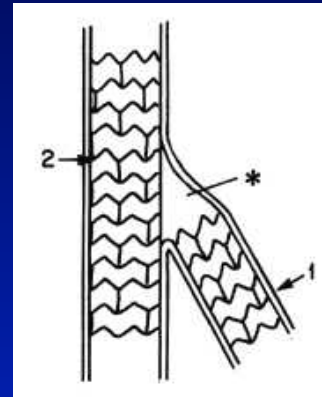
Bifurcation Lesion



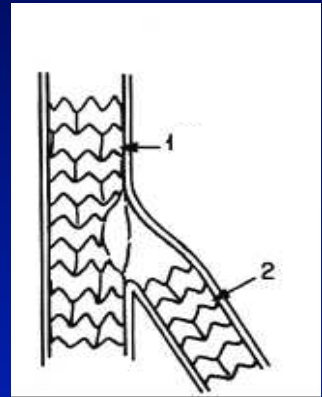
Stent+PTCA



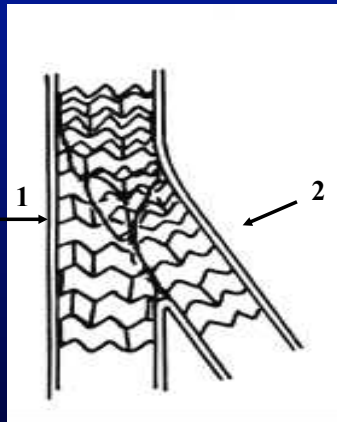
Stent+stent ("T stenting")



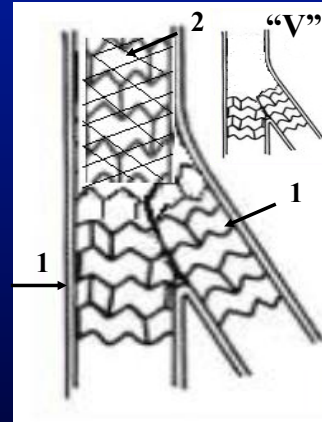
Stent+stent ("reverse-T")



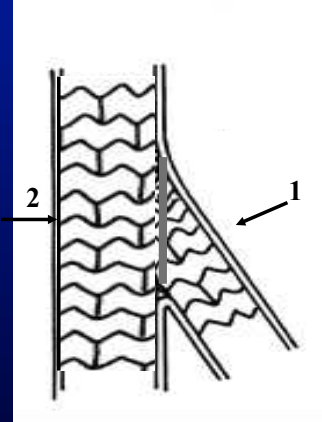
Stent+stent ("Culotte")



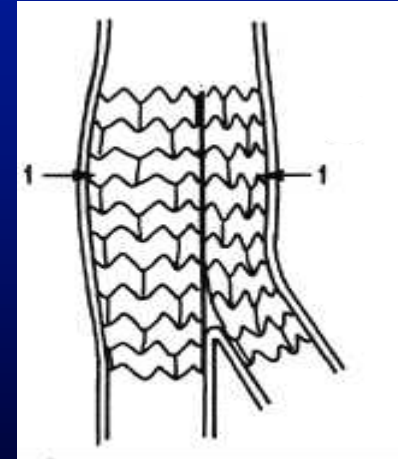
Stent+stent ("Y" or "V")



Stent+stent ("Crush")



Stent+stent ("Kissing")



Lesion Preparation for Complex Native Coronary Lesions in the DES Era

Lesions appropriate for plaque modification prior to DES

- **Calcified and undilatable/resistant**
- **Bifurcation**
- **Side-branch/Ostial**
- **Total occlusion**
- **Unprotected LM**

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Therapeutic Tactics for Complex/High Risk Native Coronary Lesions in the DES Era

Plaque modification and imaging: A³

Pre-Assessment by Angio & IVUS

Treatment decision for stent delivery, success & expansion

Simple Lesions

Alteration

Complex Lesions

Stand-alone treatment

Pre-treat: debulk / modify

DES

Post-assessment

DES

80-95%

Angio & IVUS

5-20%

Apposition / Expansion

Final results:
• High Success
• Low TLR
• Lower Bleed

IABP/LV Assist devices in
High risk Complex cases

Final results:
• Procedural complication
• Lower Bleed
• TLR?

Balloon Atherotomy

Cutting Balloon



Security & performance are engineered to:

- Reduce vessel wall expansion
- Maximize plaque compression
- Relief hoop stress

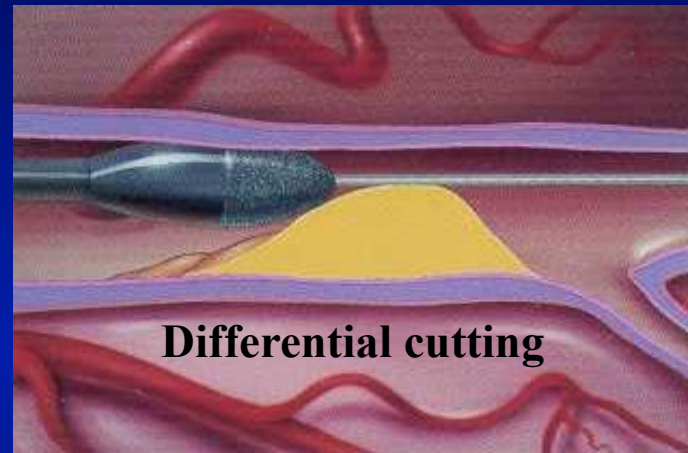
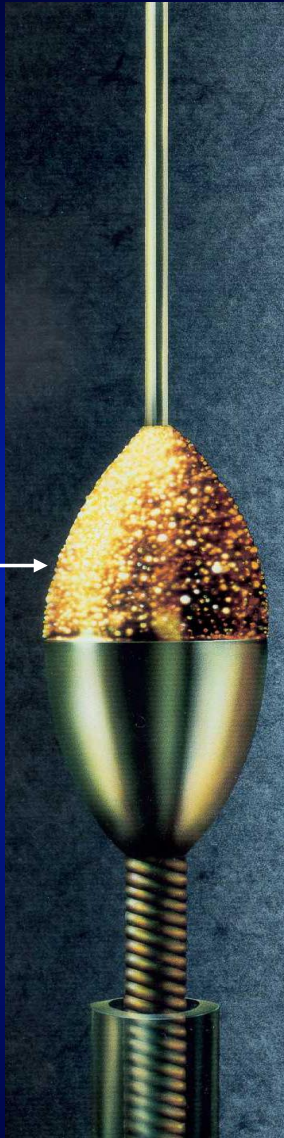
Better results with lower inflation pressure compared to plain old balloon angioplasty.

Longitudinal
microtomes

• Angiosculpt balloon

Atherectomy: Rotablator

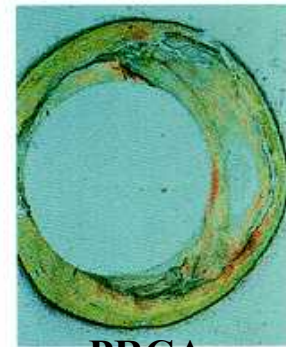
Diamond
microchips



Differential cutting



PTCA



PRCA

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LV Assist Device Support for High-Risk PCI

- **Severe LV dysfunction (LVEF <30-35%) plus**
 - **Complex Multi-vessel Disease &/or**
 - **Unprotected LM Bifurcation &/or**
 - **Last Single Remaining Vessel (specially SVG) &/or**
 - **Simple Lesion but hemodynamic compromise (low BP, high PCW or overt CHF)**
- **Complex lesions where transient closure may be catastrophic**
- **Catastrophic PCI Complications: perforation, dissection, thrombosis**
- **Large MI with hemodynamic instability**
- **Cardiogenic Shock**

Hemodynamic Support for Hemodynamic Instability Large MI & Cardiogenic Shock

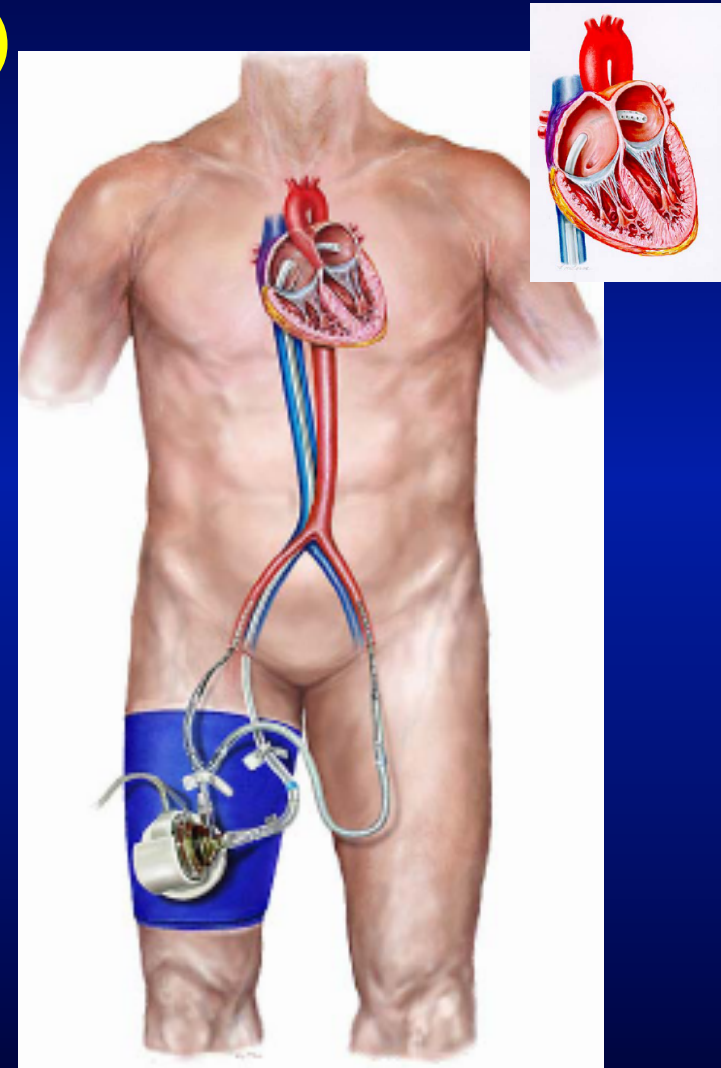
- 1. IABP**
- 2. CPS**
- 3. TandemHeart (PTVA)**
- 4. Impella Recover LP 2.5**
- 5. Other Investigational Devices (Hemopump, Reitan)**

Percutaneous Transseptal LV Assistance (PTVA)

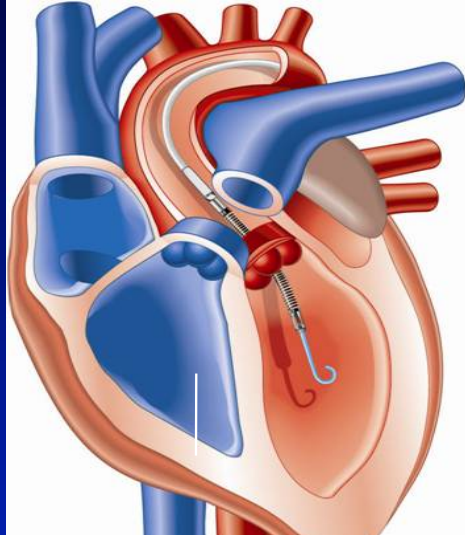
- Removes oxygenated blood from LA via transseptal cannula inserted through the femoral vein
- Returns blood via femoral artery

BENEFITS:

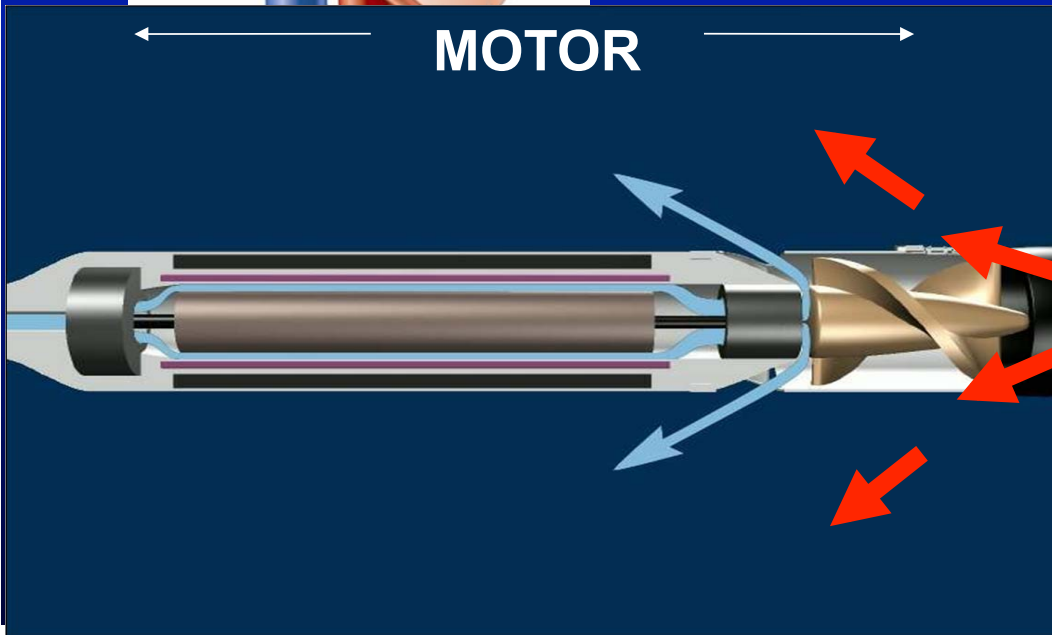
- Reduce preload
- Reduce ventricular workload
- Reduce myocardial oxygen demand
- Increase MAP
- Improve microvascular and systemic perfusion



Impella Recover LP 2.5

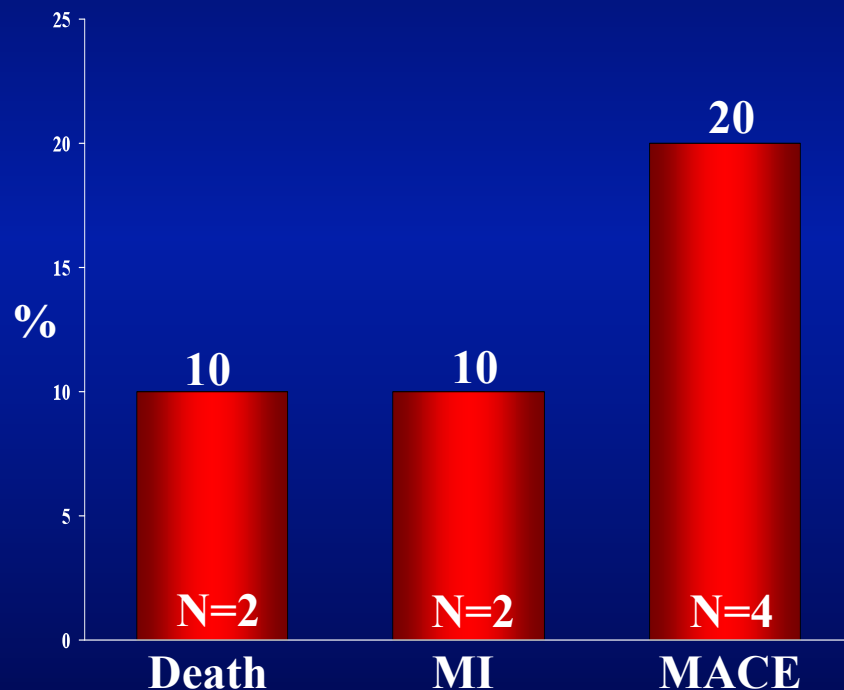


- Miniaturized technology for percutaneous access
- Fast and easy insertion: via femoral artery
- Actively unloads the ventricle
- Provides up to 2.5 L/min of flow with support up to 5 days



PROTECT I Trial: A Prospective Feasibility Trial Investigating the Use of the Impella 2.5 System in Pts Undergoing High-Risk PCI

Adverse Events at 30-Days



- The Impella 2.5 device was implanted successfully in all pts;
- The mean duration of circulatory support was 1.7 ± 0.6 h;
- Mean pump flow during PCI was 2.2 ± 0.3 l/min;
- At 30 days, the incidence of MACE was 20% (2 pts had a periprocedural MI; 2 patients died at days 12 and 14);
- There was no evidence of aortic valve injury, cardiac perforation, or limb ischemia;
- Two pts (10%) developed mild, transient hemolysis without clinical sequelae;
- None of the pts developed hemodynamic compromise during PCI.

PROTECT II Trial

A Prospective, Multicenter Randomized Controlled Trial of Impella Vs. IABP in Non-Emergent High Risk PCI Patients

n = 654

1 : 1 Randomization

Impella 2.5
n = 327

IABP
n = 327

- Primary endpoints of superiority at 30-days (Death, MI, CVA, re-revascularization, vascular surgery, cardiac surgery, ARF, \uparrow AI >1+, severe hypotension < 90 mm Hg for 5 min, CPR/V fib, Angiographic residual stenosis > 30%)
- Secondary endpoints – cardiac power output (maximum CO X mean arterial pressure)

RECOVER II Trial: A Prospective Randomized Trial Investigating the Use of IMPELLA® RECOVER® LP 2.5 System in Pts with AMI Induced Hemodynamic Instability

Study Design



Primary End-Points:

1. Death
2. Recurrent AMI
3. Target vessel revascularization
4. Stroke or TIA
5. Acute renal failure
6. Acute hepatic failure
7. Acute bowel ischemia
8. Need for major cardiovascular operation (defined as operation for repair of cardiac, thoracic aortic, abdominal aortic, or iliac artery repair or the need for a femoral artery bypass graft).

Secondary End-Points:

1. Cardiac Power Output: Maximum Increase from Baseline while on device support;
2. LVEF measured at 30 days post device implant;
3. CrCl 24 hours post device implant;
4. Cumulative dosage of vasopressors to explant;
5. % of patients weaned from ventricular assist device by day three (before 96 hours post procedure), without increased dose or number of pressor or inotropic medication support to maintain SBP >90 mmHg.;
6. Volume of fluid resuscitation to explant;
7. Time to the device explant;
8. Time to recovery (ICU time, hospitalization time);
9. Mean and AUC for serum lactate measured every 4 hours post-procedure for the first 24 hours;
10. Six minute walk test at 30-day and 3-month post device explant;
11. LV end systolic and diastolic dimension at 30 days and 3 months post device implant;
12. Failure of the investigational device to maintain a pump output of 1.0 L/min for more than five minutes at a performance level of P5 or higher in the device patients during the procedure.;
13. Failure of the IABP to augment peak diastolic pressure above the peak systolic pressure for more than five minutes in the IABP patients;
14. Need for other circulatory support device for left or right ventricular support"

LV Support during High-Risk Elective PCI:

Impact of LVEF & Lesion Complexity

