New FDA Indication for Impella® Heart Pumps
Impella® is the only percutaneous heart pump proven safe and effective for hemodynamic stabilization to enable **Heart Recovery**.

Indications now include Protected PCI and Cardiogenic Shock in the setting of AMI and Postcardiotomy.

**Heart Recovery is an improvement in heart muscle function that enables a patient to sustain quality of life at home with their native heart**
The Impella 2.5™, Impella CP®, Impella 5.0™ and Impella LD™ catheters, in conjunction with the Automated Impella Controller console, are intended for short-term use (<4 days for the Impella 2.5 and Impella CP and <6 days for the Impella 5.0 and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction (AMI) or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures with or without an intra-aortic balloon pump.

The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

* Optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without IABP
## Data Supporting FDA Indications

<table>
<thead>
<tr>
<th>Scientific Evidence</th>
<th>Total # of Patients</th>
<th># of Impella Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiogenic Shock</strong></td>
<td></td>
<td></td>
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<tr>
<td>Recover I FDA Study</td>
<td>17</td>
<td>17</td>
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<tr>
<td>ISAR Shock RCT</td>
<td>26</td>
<td>13</td>
</tr>
<tr>
<td>U.S. Impella Registry</td>
<td>401</td>
<td>401</td>
</tr>
<tr>
<td>Literature review</td>
<td>2,537</td>
<td>692</td>
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<tr>
<td><strong>Total</strong></td>
<td>2,981</td>
<td>1,123</td>
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<td><strong>Protected PCI</strong></td>
<td></td>
<td></td>
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<tr>
<td>Protect I FDA Study</td>
<td>20</td>
<td>20</td>
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<tr>
<td>Protect II FDA Study</td>
<td>452</td>
<td>225</td>
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<tr>
<td>U.S. Impella Registry</td>
<td>1,322</td>
<td>637</td>
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<tr>
<td>Literature review</td>
<td>2,537</td>
<td>756</td>
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<tr>
<td><strong>Total</strong></td>
<td>4,331</td>
<td>1,638</td>
</tr>
</tbody>
</table>

*24,000 Patients from FDA medical device reporting (MDR) database*
Hemodynamic Stabilization with Impella

- Unloads Left Ventricle & Coronary Perfusion
- End Organ Perfusion
- Right Side Support
- Escalation & Ambulation

Seyfarth et al., JACC, 2008
Remmelink M et al., Cath Card Interv. 2007
Lam K. et al., Clin Res Cardiol, 2009
Casassus et al., JOIC, 2015
Anderson MB. et al., J HT Lg Transplant. 2015
Lima B. et al., Am J Cardiol 2016
Current Challenges in the Treatment of Cardiogenic Shock
INCIDENCE OF CARDIOGENIC SHOCK GROWING

Cardiogenic Shock in STEMI Increasing

STEMI Cardiogenic Shock in Medicare Age Increasing

Age ≥65 only, excludes non-Medicare population

1. Dhaval Kolte et al. J Am Heart Assoc 2014
2. Centers for Medicare and Medicaid database, MEDPAR FY14
Cardiogenic Shock Remains Leading Cause of Mortality in Acute Myocardial Infarction

High In-Hospital Mortality During AMI Cardiogenic Shock¹

N = 23,696

… and Ongoing Hazard Post Discharge after AMI Cardiogenic Shock²

N = 112,668

2. Shah, et al. JACC 2016 NCDR Registry
Mortality in PCI with Cardiogenic Shock Remains a Clinical Challenge

In-Hospital Mortality
AMI Cardiogenic Shock with PCI

N = 32,598

<table>
<thead>
<tr>
<th>Year</th>
<th>Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-2006</td>
<td>28%</td>
</tr>
<tr>
<td>2011-2013</td>
<td>31%</td>
</tr>
</tbody>
</table>

p < 0.0001

AMI Cardiogenic Shock with PCI only: Overall mortality >50%

Wayangankar, et al. JACC Int 2016 CATH-PCI Registry
AMI Shock Often Treated in Community Hospitals

AMI Cardiogenic Shock with PCI

N = 56,497

90% Private/Community
10% Academic/ Gov’t

2005-06
>500 PCI: 69%
<500 PCI: 31%

2011-13
>500 PCI: 52%
<500 PCI: 48%
High dose Vasopressors/Inotropes Associated With Increased In-Hospital Mortality

Mortality Risk
N = 3462

- No Inotrope: 2%
- Low Dose: 3%
- Moderate Dose: 7.5%
- One High Dose: 21%
- Two High Dose: 42%
- Three High Dose: 80%

Samuels LE et al., J Card Surg. 1999
**IABP in AMI Cardiogenic Shock: No Hemodynamic or Survival Benefit**

### IABP SHOCK I
Randomized Controlled Trial

- **N** = 40

<table>
<thead>
<tr>
<th>Time (Hours)</th>
<th>IABP (n=19)</th>
<th>Medical Therapy (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>48</td>
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<tr>
<td>72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>96</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CPO = MAP x Cardiac Output x 0.0022

### IABP-SHOCK II
Randomized Controlled Trial

- **N** = 600

<table>
<thead>
<tr>
<th>Time After Randomization (Days)</th>
<th>IABP (n=301)</th>
<th>Medical Therapy (n=299)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
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<tr>
<td>15</td>
<td></td>
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<tr>
<td>20</td>
<td></td>
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<tr>
<td>25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

log-rank, p=0.92

41.3% vs 39.7%

### IABP Increased Hazard Risk of Stroke, Downgraded to Class III (harm), Level of Evidence A, ESC STEMI Guidelines 2014

2. Thiele H et al. NEJM 2012 - Clinicaltrial.gov # NCT00491036
New Cardiogenic Shock Indicated Therapy: Impella
Patients That Benefit from Impella®

Protected PCI

- Patient Comorbidities
- Complex Coronary Artery Disease
- Hemodynamic Compromise

Cardiogenic Shock Therapy

- Myocardial Recovery Patients
- Cardiac Output
- MAP
- End Organ Perfusion
- Death Spiral of Cardiogenic Shock

Protected PCI Patients
IMPELLA® HEART PUMP: HOW IT WORKS

Placement in Left Ventricle

Outflow

Impeller and blood outflow

Inflow
**HEMODYNAMICS OF IMPELLA® IN AMI CARDIOGENIC SHOCK**

**Case Example**

- 49 Yrs, Male
- Cold, Clammy skin
- Tachycardia
- Cardiac Output: 3.3 L/min
- Wedge Pressure: 22 mmHg
- 75% Left main
- MAP 51 mmHg, LVEDP 28 mmHg

---

* Not all patients will experience the same clinical outcomes or hemodynamic responses
Improvement in Cardiac Index

ISAR SHOCK Randomized Controlled Trial

(H/min/m²)

**Impella 2.5™**

**Native Heart**

Pre-Support 1.71±0.45

On Impella 2.20±0.64

**Impella 2.5**

P= 0.02

Augmented CI

Ventricular Unloading

**IABP**

Pre-Support 1.73±0.59

On IABP 1.84±0.71

N.S.

N=26

Seyfarth et al., JACC, 2008
The catheter based VAD Registry is a worldwide, multicenter, IRB approved, monitored clinical registry of all patients at participating sites; registry data is used for FDA PMA submissions.

**Improved Myocardial Perfusion with Impella®**

**Coronary Flow Velocity (cm/s)**

<table>
<thead>
<tr>
<th>conditions</th>
<th>n=11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Support</td>
<td>61</td>
</tr>
<tr>
<td>On Support</td>
<td>72</td>
</tr>
<tr>
<td>Increase in %</td>
<td>18%</td>
</tr>
</tbody>
</table>

*p<0.0001*

**Occluded RCA/LCX Territory**

Bedside planar images with gamma camera

**CTO of LCX and RCA untreated**

1. Remmelink, et. al. CCI, 2007
**Improved End Organ Perfusion With Impella®**

**Reduction of Blood Lactate Concentration**

P < .0001

<table>
<thead>
<tr>
<th>Blood Lactate (mmol/L)</th>
<th>Baseline (n=19)</th>
<th>Day 1 (n=17)</th>
<th>Day 2 (n=16)</th>
<th>Day 3 (n=15)</th>
<th>Day 4 (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.37</td>
<td>3.91</td>
<td>2.40</td>
<td>1.78</td>
<td>1.59</td>
<td></td>
</tr>
</tbody>
</table>

Numbers of days from Impella Implant

Changes in Sublingual Microcirculation

**Impella OFF**
Baseline prior to Impella support

**Impella ON**
After 48hrs of Impella support

Sidestream dark field (SDF) imaging used to study sublingual microcirculation

Lam, et. al., Clin Res Cardiol, 2009,
IMPROVING OUTCOMES IN AMI CARDIOGENIC SHOCK WITH IMPELLA®

BEST PRACTICES LEARNED FROM CLINICAL EXPERIENCE
Reverse the Cardiogenic Shock Spiral

Impella Now FDA Approved for Cardiogenic Shock Therapy

Cardiogenic Shock Identifiers (Protocol elements)
- SBP <90 mmHg or on Inotropes/Pressors
- Cold, clammy, tachycardia
- Lactate elevated >2 mmol/L

Cardiogenic etiology evaluation
- EKG (STEMI / NSTEMI)
- Echocardiography
- If available, PA catheter, Cardiac Output, CPO, CI, PCWP, SvO2

Cardiac Output
MAP
End Organ Perfusion
Coronary Perfusion
Ischemia
End Organ Failure
Progressive Myocardial Dysfunction
Death Spiral of Cardiogenic Shock

Myocardial Recovery Patients
Reverse Spiral
The catheter-based VAD Registry is a worldwide, multicenter, IRB approved, monitored clinical registry of all patients at participating sites; registry data is used for FDA PMA submissions.

* cvAD Registry Data of Patients Undergoing PCI for Acute Myocardial Infarction Complicated by Cardiogenic Shock as of September 2015.
Timing of Support Impacts Outcomes

30 Day Survival

cVAD Registry*
N = 154

Survival Rate

Impella Pre - PCI

IABP/Inotropes Pre-PCI

Log-Rank, p=0.004

Door to Balloon Metric - Cardiogenic Shock & hemodynamic support are excluded from Door to Balloon (DTB) metrics. Source: CMS, SCAI & ACC

The catheter based VAD Registry is a worldwide, multicenter, IRB approved, monitored clinical registry of all patients at participating sites; registry data is used for FDA PMA submissions.

O’Neill, et. al, J Interven Cardiol, 2014
Myocardial Recovery is the Most Likely Outcome with Impella®

The Impella Device for Acute Mechanical Circulatory Support in Patients in Cardiogenic Shock

Anthony Lemaire, MD, Mark B. Anderson, MD, Leonard Y. Lee, MD, Peter Scho, MD, Thomas Prendergast, MD, Andrew Goodman, Ann Marie Logan, RN, Alan Spontitz, MD, MPA, and George Batsides, MD

Department of Cardiothoracic Surgery, Robert Wood Johnson University Hospital, The University of Medicine and Dentistry of New Jersey, Newark, New Jersey, and Albertsons Inc, Danvers, Massachusetts

Background: Acute cardiogenic shock is associated with high mortality rates. Mechanical circulatory devices have been increasingly used in this setting for hemodynamic support. Impella is a percutaneous centrifugal pump that is capable of providing high flow support for patients. This study was conducted to determine the outcome of patients who have undergone placement of the Impella device for acute cardiogenic shock in our institution.

Methods: A retrospective review of 47 patients who underwent placement of the Impella device was performed from January 1, 2006, to December 31, 2011. Records were evaluated for demographics, operative details, and postoperative outcomes. Operative mortality was defined as death within 30 days of the operation. Results: The patients (33 male) were an average age of 68 years. The Impella device was placed in 47 patients (23 L1, 24 L2). The 30-day survival rate was 75%. Of the 47 patients, 36 (80%) received the Impella L1 and the rest the L2 device. Ventricular function recovered in 14 of 47 patients (25%), and the device was removed, with complete recovery of ventricular function, in 1 of 47 patients. The postoperative mortality rate was 25% (12 of 47 patients). Complications occurred in 14 patients (100%) consisting of device malfunction, high pump pressures, tube fracture, and groin hematomas.

Conclusions: This is one of the longest series of patients undergoing placement of the Impella device for acute cardiogenic shock. Our outcomes showed improved results compared with historical data. Myocardial recovery was accomplished in most patients. Finally, the 30-day mortality and complication rate was acceptable in these critically ill patients. These findings were all achieved with the Impella device in a less invasive method.

30 Day Survival = 75%

N=47 underwent Impella placement from Jan 1, 2006 to Dec 31, 2011

- Bridge to Bridge (12%)
- Recovery (88%)

75%
60%
45%
30%
15%
0%
Identify (Protocols)
• SBP <90 mmHg or on Inotropes/Pressors
• Cold, clammy, tachycardia
• Lactate elevated >2 mmol/L

Stabilize Early
Reduce Door to Unloading Time (DTU)
• Impella Support pre-PCI
• Reduce Inotropes/Pressors

Complete Revascularization
• PCI Guidelines based in Cardiogenic Shock

Assess for Myocardial Recovery (Weaning and Transfer Protocols)
• ↑ Cardiac Output
• ↑ Cardiac Power Output
• ↑ Urine Output
• ↓ Lactate
• ↓ Inotropes

Myocardial Recovery

No Recovery Escalate & Ambulate
• Ongoing Left heart failure
• Assess for Right heart failure

Cardiogenic etiology evaluation
• EKG (STEMI / NSTEMI)
• Echocardiography
• If available, PA catheter, Cardiac Output, CPO, CI, PCWP, SvO₂
Systematic Review of Impella® Cost Effectiveness

Reduction of Length of Stay for PVADs

Elective and Urgent Setting
- 2 days  
- 2 days  
- 2 days  
- 2.5 days

Emergent Setting
- 4 days  
- 5 days  
- 10 days  
- 11 days

Hospital Days

1. Gregory et al. [28]  
2. Gregory et al. [27]  
3. Aryana et al. [44]  
4. Wohns et al. [46]  
5. Maini et al. [29]  
6. Cheung et al. [31]  
7. Gregory et al. [27]  
8. Maini et al. [29]
Population Studies Show Reduced Mortality with PVAD in AMI Cardiogenic Shock

Mortality AMI Cardiogenic Shock Pre/Post PVAD Era

- No PVAD: 52% (2004 - 2007)
- PVAD Era: 43% (2008 - 2011)

p = 0.012

N = 11,887

Mortality in AMI Cardiogenic Shock ECMO/eLVAD vs. PVAD

- Surgical MCS: 56% (p < 0.001)
- PVAD: 42%

N = 1188

Co-morbidity Matching

Stretch, et. al JACC 2014 National Inpatient Sample
CONCLUSIONS

• Overall mortality rates in AMI Cardiogenic Shock with inotropic/pressor or IABP support have not improved, and may be increasing in PCI

• Protocols for early identification, early support, and changing the focus to myocardial recovery for better outcomes and quality of life are needed

• Hemodynamic support with Impella® promotes myocardial recovery by stabilizing hemodynamics, unloading the left ventricle, and perfusing the coronaries and end organs

• Treatment of cardiogenic shock with Impella is one of the most cost effective therapies available in clinical practice
ADDITIONAL INFORMATION
**Clinical Society Guidelines for Impella® Therapy**

<table>
<thead>
<tr>
<th>Clinical Society Guideline Populations (SCAI, ACCF, HFSA, STS, ISHLT, HRS)</th>
<th>Class</th>
<th>Latest Update</th>
<th>Impella FDA Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI in Cardiogenic Shock</td>
<td>I</td>
<td>2013</td>
<td>2016</td>
</tr>
<tr>
<td>Multi-organ failure, Cardiogenic Shock</td>
<td>I</td>
<td>2013</td>
<td>2016</td>
</tr>
<tr>
<td>PCI in Low Ejection Fraction, Complex CAD</td>
<td>IIb</td>
<td>2011*</td>
<td>2015</td>
</tr>
<tr>
<td>Bridge to Recovery or Decision, Cardiogenic Shock</td>
<td>IIa</td>
<td>2013</td>
<td>2016</td>
</tr>
<tr>
<td>STEMI and Cardiogenic Shock</td>
<td>IIb</td>
<td>2013</td>
<td>2016</td>
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<tr>
<td>STEMI and Urgent CABG</td>
<td>IIa</td>
<td>2013</td>
<td>2016</td>
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<tr>
<td>Acutely Decompensated Heart Failure</td>
<td>IIa</td>
<td>2012</td>
<td>TBD</td>
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<tr>
<td>Consensus Document on Hemodynamic Support</td>
<td>N/A</td>
<td>2015</td>
<td>2015/16</td>
</tr>
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</table>

**Categories referencing Impella include Percutaneous LVAD, PVAD, Non-durable MCS, TCS and percutaneous MCSD**

*Excludes Protect II Randomized Controlled Trial, and FDA PMA approval studies due to timing of available data in 2011.
### Randomization in AMI CS is Challenging

**Prospective Impella Trials In Emergent Settings**

<table>
<thead>
<tr>
<th>Study</th>
<th>Trial ID</th>
<th>Condition</th>
<th>Pts Required (n)</th>
<th>Pts Enrolled (n)</th>
<th>Duration (months)</th>
<th>Status</th>
<th>Reason for Discontinuation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FRENCH TRIAL</strong> (2006)</td>
<td>NCT00314847</td>
<td>AMI CS</td>
<td>200</td>
<td>19</td>
<td>52</td>
<td>Discontinued</td>
<td>Low Enrollment</td>
</tr>
<tr>
<td><strong>ISAR-SHOCK</strong> (2006)</td>
<td>NCT00417378</td>
<td>AMI CS</td>
<td>26</td>
<td>26</td>
<td>19</td>
<td>Completed</td>
<td>N/A</td>
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<tr>
<td><strong>IMPRESS</strong> (2007)</td>
<td>NTR1079 trialregister.nl</td>
<td>STEMI Pre-CS</td>
<td>130</td>
<td>18</td>
<td>22</td>
<td>Discontinued</td>
<td>Low Enrollment</td>
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<tr>
<td><strong>RECOVER I FDA</strong> (2008)</td>
<td>NCT00596726</td>
<td>PCCS</td>
<td>Up to 20</td>
<td>17</td>
<td>28</td>
<td>Completed</td>
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<tr>
<td><strong>RECOVER II FDA</strong> (2009)</td>
<td>NCT00972270</td>
<td>AMI CS</td>
<td>384</td>
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<td>Discontinued</td>
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<td><strong>RELIEF I</strong> (2010)</td>
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<td>33</td>
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<tr>
<td><strong>DANSHOCK</strong> (2012)</td>
<td>NCT01633502</td>
<td>AMI CS</td>
<td>360</td>
<td>~50</td>
<td>40</td>
<td>Enrolling</td>
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</tr>
</tbody>
</table>
THE HEMODYNAMIC SUPPORT EQUATION

- Circulatory Support (Systemic Perfusion)
- Ventricular Unloading
- Coronary Perfusion

Mean Arterial Pressure

LV-ESP & EDP
Ao Pulse Pressure

MAP - LVEDP

Kapur NK et al. Submitted
Cardiac Power Output: #1 Correlate to Mortality in AMI Cardiogenic Shock

Cardiac Power Output
(MAP x Cardiac Output x 0.0022)

Est. In-Hospital Mortality

(n=189)

Fincke, et. al. JACC, 2004 SHOCK TRIAL
Support Strategy (N=154)

- No support Pre-PCI (N=38)
  - PCI
  - Impella Post PCI

- IABP Pre-PCI (N=53)
  - PCI
  - Impella Post PCI

- Impella Pre-PCI (N=63)
  - PCI
  - Continue Impella

Survival to discharge

- 39.5% (N=38)
- 41.5% (N=53)
- 65.1% (N=63)

P=0.016

Clinical Outcomes by Support Strategy

O'Neill, et. al, J Interven Cardiol, 2014

cVAD Registry
Left Ventricular Ejection Fraction
(n=12)

Pre-Impella: 27 ± 9%
Day 7 post Impella: 34 ± 7%
Day 28 post Impella: 44 ± 10%

*p < .0001

Casassus, et. al, J Interven Cardiol, 2015
**Impella® Reduces Need for Inotropes/Pressors**

**Impella 2.5™**
Reduction in Inotropes/Pressors in 24 Hours

- ISAR-SHOCK RCT¹
  - N=25

- IABP: 44%
- Impella: 75%

**Impella 5.0™**
Reduction in Inotropes/Pressors Over days

- RECOVER I FDA IDE Study²
  - (N=16)

1. Seyfarth et al. JACC 2008
DECREASE IN INOTROPES/PRESSORS IN RIGHT HEART FAILURE

Average time of Impella RP support

Pump Implant

Anderson MB, et al., J Mt Lg Transplant. 2015
HEMODYNAMIC EFFECTS OF IMPELLA® SUPPORT

Inflow (ventricle)

Outflow (aortic root)

aortic valve

Flow

MAP

LVEDP and LVEDV

Wall Tension

Mechanical Work

Microvascular Resistance

Coronary Perfusion

O₂ Supply

O₂ Demand

End Organ Perfusion

Cardiac Power Output

Unloading to Myocardial Recovery

References:
- Mendoza DD, et al. AMJ 2007
LIMITATIONS OF CONVENTIONAL THERAPY

Mortality Risk with Inotropes/Vasopressors

N = 3462

- No Inotrope: 2%
- Low Dose: 3%
- Moderate Dose: 7.5%
- One High Dose: 21%
- Two High Dose: 42%
- Three High Dose: 80%

IABP-SHOCK II Randomized Controlled Trial

N = 600

- IABP (n=301): 41.3%
- Medical Therapy (n=299): 39.7%

1- Samuels LE et al., J Card Surg. 1999
2- Thiele H et al. NEJM 2012 - Clinicaltrial.gov # NCT00491036
INDICATION & SAFETY INFORMATION
**IMPELLA® DEVICE INDICATION & SAFETY INFO.**

**INDICATIONS FOR USE**

**Protected PCI**
The Impella 2.5™ and Impella CP® Systems are temporary (≤6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 and Impella CP Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

**Cardiogenic Shock**
The Impella 2.5™, Impella CP®, Impella 5.0™, and Impella LD™ Catheters, in conjunction with the Automated Impella Controller (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short-term use (≤4 days for the Impella 2.5 and Impella CP, and ≤6 days for the Impella 5.0, and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

**Important Risk Information for Impella devices**

**CONTRAINDICATIONS**
The Impella 2.5, Impella CP, Impella 5.0 and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm² or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade*

* This condition is a contraindication for the cardiogenic shock indication only.

**POTENTIAL ADVERSE EVENTS**
Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices. Visit [www.protectedpci.com/hcp/information/isi](http://www.protectedpci.com/hcp/information/isi) and [www.cardiogenicshock.com/hcp/information/isi](http://www.cardiogenicshock.com/hcp/information/isi) to learn more.
RIGHT-SIDE SUPPORT – INDICATION & SAFETY INFO.

INDICATIONS FOR USE
The Impella RP® is indicated for providing circulatory assistance for up to 14 days in pediatric or adult patients with a body surface area ≥ 1.5 m² who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

Important Risk Information for Impella RP

CONTRAINDICATIONS
The Impella RP is contraindicated for use with patients experiencing any of the following conditions: Pulmonary artery wall disorders precluding placement or correct positioning of the Impella RP device; Anatomic conditions precluding insertion of the pump; Tricuspid or pulmonic valve abnormalities including: mechanical valves, severe stenosis or regurgitation; Mural thrombus of the right atrium or vena cava; Other illnesses or therapy requirements precluding use of the pump; Presence of a vena cava filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter.

POTENTIAL ADVERSE EVENTS
Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device Malfunction, Hemolysis, Hepatic failure, Insertion site infection, Perforation, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system) complication, Tricuspid valve injury, Vascular injury, Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella RP.

Visit [www.abiomed.com/impella/impella-rp](http://www.abiomed.com/impella/impella-rp) to learn more.