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>
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<tr>
<td>U.S. Impella Registry</td>
<td>401</td>
<td>401</td>
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<tr>
<td>Literature review</td>
<td>2,537</td>
<td>692</td>
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<td><strong>Total</strong></td>
<td>2,981</td>
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<td><strong>Protected PCI</strong></td>
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<td>Protect I FDA Study</td>
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<tr>
<td>Protect II FDA Study</td>
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<tr>
<td>U.S. Impella Registry</td>
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<tr>
<td>Literature review</td>
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<td>756</td>
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<tr>
<td><strong>Total</strong></td>
<td>4,331</td>
<td><strong>1,638</strong></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

- Right Side Impella RP
- Left Side Impella 2.5/CP/5.0

- Seyfarth et al., JACC, 2008
- Remmelink M et al., Cath Card Interv. 2007
- Lam K et al., Clin Res Cardiol. 2009
- Casassus et al., JOWC, 2015
- Anderson MB et al., J Mt 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 NATIONWIDE INPATIENT SAMPLE
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 Shock

\[ N = 23,696 \]

\[ \begin{array}{c}
\text{Death Rate, %} \\
\hline
100 \\
90 \\
80 \\
70 \\
60 \\
50 \\
40 \\
30 \\
20 \\
10 \\
0
\end{array} \]

\[ \begin{array}{c}
\text{DAYS SINCE HOSPITAL DISCHARGE} \\
\hline
0 \\
10 \\
20 \\
30 \\
40 \\
50 \\
60
\end{array} \]

... and Ongoing Hazard Post Discharge after AMI Cardiogenic Shock

\[ N = 112,668 \]

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

<table>
<thead>
<tr>
<th>Year</th>
<th>&gt;500 PCI</th>
<th>&lt;500 PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-06</td>
<td>69%</td>
<td>31%</td>
</tr>
<tr>
<td>2011-13</td>
<td>52%</td>
<td>48%</td>
</tr>
</tbody>
</table>

Wayangankar et al. JACC Interventions 2016 CATH-PCI REGISTRY
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**
- **CPO = MAP x Cardiac Output x 0.0022**

- IABP (n=19)
- Medical Therapy (n=21)

**IABP-SHOCK II**
Randomized Controlled Trial

- **N = 600**

- IABP (n=301)
- Medical Therapy (n=299)

Log-rank, p=0.92

IABP Increased hazard risk of stroke, downgraded to Class III (harm), Level of Evidence A, ESC STEMI Guidelines 2014

1- Prondzinsky R. et al. Jn Critical Care Medicine IABP SHOCK I 2010 – Clinicaltrial.gov # NCT00469248

2- Thiele H et al. NEJM 2012 - Clinicaltrial.gov # NCT00491036
NEW CARDIOGENIC SHOCK INDICATED THERAPY: **Impella**
Patients That Benefit from Impella®

Protected PCI
- Protected PCI Patients
- Complex Coronary Artery Disease
- Hemodynamic Compromise

Cardiogenic Shock Therapy
- Myocardial Recovery Patients
  - Cardiac Output
  - MAP
  - End Organ Perfusion
  - Reverse Spiral
  - Death Spiral of Cardiogenic Shock
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
Hemodynamic Stability & LV Unloading with Impella®

Improvement in Cardiac Index
ISAR SHOCK Randomized Controlled Trial
(L/min/m²)

Impella 2.5

N=26

1.71 ± 0.45
Pre-Support

2.20 ± 0.64
P= 0.02
Impella 2.5

1.73 ± 0.59
1.84 ± 0.71
IABP

1.73 ± 0.59
On Impella

Augmented CI
Ventricular Unloading

N.S.

Seyfarth et al., JACC, 2008
Hemodynamic Improvement Impella - cVAD Registry

- **MAP**
  - Pre-Support: 62.7 ± 19.2
  - On Support: 94.4 ± 23.1
  - Increase: 51% (n=143)
  - p<0.0001

- **Cardiac Output**
  - Pre-Support: 3.4 ± 1.3
  - On Support: 5.3 ± 1.7
  - Increase: 56% (n=23)
  - p<0.0001

- **Cardiac Power Output** (MAP x CO x 0.0022)
  - Pre-Support: 0.48 ± 0.17
  - On Support: 1.06 ± 0.48
  - Increase: 120% (n=23)
  - p<0.0001

- **PCWP**
  - Pre-Support: 31.9 ± 11.1
  - On Support: 19.2 ± 9.7
  - Decrease: 40% (n=25)
  - p<0.0001

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, 2013.
**IMPROVED MYOCARDIAL PERFUSION WITH IMPELLA®**

**Coronary Flow Velocity**

- **Pre-Support:** 61 cm/s
- **On Support:** 72 cm/s

*Analysis:*

- **Change:** Increase of 18% (p<0.0001)

**Occluded RCA/LCX Territory**

1. Remmelink, et. al. CCI, 2007
Improvement in End Organ Perfusion with Impella®

Reduction of Blood Lactate Concentration

P < .0001

Blood Lactate (mmol/L)

<table>
<thead>
<tr>
<th>Day</th>
<th>Blood Lactate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6.37</td>
</tr>
<tr>
<td>Day 1</td>
<td>3.91</td>
</tr>
<tr>
<td>Day 2</td>
<td>2.40</td>
</tr>
<tr>
<td>Day 3</td>
<td>1.78</td>
</tr>
<tr>
<td>Day 4</td>
<td>1.59</td>
</tr>
</tbody>
</table>

Numbers of days from Impella Implant

Casassus, et. al, J Interven Cardiol, 2015
IMPROVED END ORGAN PERFUSION WITH IMPELLA

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

Coronary Perfusion
End Organ Perfusion
MAP
Cardiac Output

Myocardial Recovery Patients
Reverse Spiral
Death Spiral of Cardiogenic Shock

Progressive Myocardial Dysfunction
End Organ Failure
Ischemia
The Global cVAD Registry™

Reported Usage at Registry Sites
N=2704

- HRPCI Elective & Urgent 47% (n=1275)
- Cardiogenic Shock 40% (n=1090)
- Other 13% (n=339)

Characteristics of AMI/CS Patients
N=485*

- STEMI 69%
- Cardiogenic Shock on Admission 59%
- Cardiac Arrest 54%
- IABP initiated prior to Impella 38%
- Cardiogenic Shock ≥ 12 hours 33%
- Anoxic Brain Injury 20%

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

Impella Pre - PCI

IABP/Inotropes Pre-PCI

Survival Rate

Log-Rank, p=0.004

Days from initiation of Impella

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 Scholz, MD, Thomas Prendergast, MD, Andrew Goodman, Ann Marie Lozano, RN, Alan Spontitz, MD, MPA, and George Rabinov, MD

Department of Cardiothoracic Surgery, Robert Wood Johnson University Hospital, The University of Medicine and Dentistry of New Jersey, New Brunswick, New Jersey, and Alimera, Inc., Danbury, Connecticut.

Background: Acute cardiogenic shock is associated with high mortality rates. Mechanical circulatory support devices have been increasingly used in this setting for hemodynamics and to support myocardial recovery. Impella is a micro axillary ventricular assist device that can be inserted using a percutaneous technique. This study was conducted to determine the outcome of patients who underwent implantation 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' mean age was an average age of 67 years. Survival was 75% at 30 days, 60% at 3 months, and 45% at 1 year. Of the 47 patients, 46 (98%) received the Impella 5.0 and the rest the 2.5 device. Ventricular function recovered in 34 of 47 patients (72%), and the device was removed, with subsequent recovery of ventricular function. Complications occurred in 14 patients (30%), consisting of device malfunction, high purge pressures, valve fracture, and graft hematomas.

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

Bridge to Bridge (12%)

Recovery (88%)

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

30 Day Survival = 75%

75%

60%

45%

30%

15%

0%

4/34
**Impella® Best Practices in AMI Cardiogenic Shock**

**Identify (Protocols)**
- SBP <90 mmHg or on Inotropes/Pressors
- Cold, clammy, tachycardia
- Lactate elevated >2 mmol/L

**Stabilize Early**
- 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, P=0.008
  - -2 days, P=0.01
  - -2 days, P=0.04
  - -2.5 days, P=0.338

- Emergent Setting
  - -4 days, P=0.055
  - -5 days, P=N/A*
  - -10 days, P=0.05
  - -11 days, P=0.003

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: 2004-2007
  - Mortality: 52%
  - p=0.012
  - N=11,887
- PVAD Era: 2008-2011
  - Mortality: 43%

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
<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>
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<tbody>
<tr>
<td>PCI in Cardiogenic Shock</td>
<td>I</td>
<td>2013</td>
<td>2016</td>
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<tr>
<td>Multi-organ failure, Cardiogenic Shock</td>
<td>I</td>
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<td>2016</td>
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<tr>
<td>PCI in Low Ejection Fraction, Complex CAD</td>
<td>IIb</td>
<td>2011*</td>
<td>2015</td>
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<tr>
<td>Bridge to Recovery or Decision, Cardiogenic Shock</td>
<td>IIa</td>
<td>2013</td>
<td>2016</td>
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<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>
</tr>
<tr>
<td>Acutely Decompensated Heart Failure</td>
<td>IIa</td>
<td>2012</td>
<td>TBD</td>
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<td>Consensus Document on Hemodynamic Support</td>
<td>N/A</td>
<td>2015</td>
<td>2015/16</td>
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</tbody>
</table>

**Categories referencing Impella include Percutaneous LVAD, PVAD, Non-durable MCS, TCS and percutaneous MCS.D
* 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>
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<tbody>
<tr>
<td>FRENCH TRIAL</td>
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<td>AMI CS</td>
<td>200</td>
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<td>Low Enrollment</td>
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<td>ISAR-SHOCK</td>
<td>NCT00417378</td>
<td>AMI CS</td>
<td>26</td>
<td>26</td>
<td>19</td>
<td>Completed</td>
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<td>IMPRESS</td>
<td>NTR1079</td>
<td>STEMI Pre-CS</td>
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<tr>
<td>RECOVER I FDA</td>
<td>NCT00596726</td>
<td>PCCS</td>
<td>Up to 20</td>
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<td>Completed</td>
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<td>RECOVER II FDA</td>
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<td>RELIEF I</td>
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<td>DANSHOCK</td>
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<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)
  - Mean Arterial Pressure

- Ventricular Unloading
  - LV-ESP & EDP
  - Ao Pulse Pressure

- Coronary Perfusion
  - 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)

Fincke, et. al. JACC, 2004 SHOCK TRIAL
**Impella® Promotes Functional Recovery**

Left Ventricular Ejection Fraction  
(n=12)

\[ p < 0.0001 \]

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

**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

Pump Implant

Average time of Impella RP support

Anderson MB et al., J Heart Lung Transplant. 2015
LIMITATIONS OF CONVENTIONAL THERAPY

Mortality Risk with Inotropes/Vasopressors¹
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 Trial²
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
PROTECTED PCI™ – INDICATION & SAFETY INFO.

INDICATION FOR USE
The Impella 2.5™ System is a temporary (≤ 6 hours) ventricular support device 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 System 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.

CONTRAINDICATIONS
The Impella 2.5™ is 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 2.5™ System

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 the Impella 2.5™. Visit www.protectedpci.com/hcp/information/isi to learn more.
CARDIOGENIC SHOCK – INDICATION & SAFETY INFO.

INDICATION FOR USE
The Impella 2.5™, Impella CP®, Impella 5.0™ and Impella LD™ catheters, in conjunction with the Automated Impella Controller, 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 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.* 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.

CONTRAINDICATIONS
The Impella devices are contraindicated for use in this indication for patients experiencing 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 (with respect to the Impella 2.5)) or (graded as ≥ +2 equivalent to an orifice area of 1.5 cm² or less (with respect to the Impella CP, Impella 5.0 and Impella LD)); 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; Ongoing CPR; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD); Left ventricular rupture; and Cardiac tamponade.

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

The institution of circulatory support using Impella has not been studied in the following conditions: presence of irreversible end-organ failure; and presence of severe anoxic brain injury

In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with the use of Impella in this indication. Visit www.cardiogenicshock.com/isi to learn more.
RIGHT-SIDE SUPPORT – INDICATION & SAFETY INFO.

INDICATION FOR USE
The Impella RP® System 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.

CONTRAINDICATIONS
The Impella RP is contraindicated for use with patients experiencing any of the following conditions: (1) Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP device; (2) Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid valve or pulmonary valve; (3) Mural thrombus of the right atrium or vena cava; (4) Anatomic conditions precluding insertion of the pump; (5) Other illnesses or therapy requirements precluding use of the pump; and (6) 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
Additionally, potential for the following risks has been found to exist with the use of the Impella RP: 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.

The Impella RP is approved for use as a Humanitarian Device. Its effectiveness for the above indication has not been demonstrated.