INDICATIONS FOR USE

PROTECTED PCI

The Impella 2.5® and Impella CP® Systems are a 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 and www.cardiogenicshock.com/hcp/information/isi to learn more.
Introduction

Meeting the challenging needs of the complex cardiovascular patient is an increasing burden for hospitals and health care providers. Today’s challenging clinical cardiovascular setting includes a patient population with rising multi-morbid conditions. This increasing multi-morbid patient population contributes to the increased number of cardiovascular patients who may require complex care.

With this rise in multi-morbidities, the number of cardiovascular patients that may require a high-risk procedure is expected to increase. Coronary Artery Disease (CAD) incidence is expected to climb 47 percent over the next 25 years. According to The Advisory Board Company’s *Guide to Protected PCI in High-risk Cardiovascular Patients*, it is this “simultaneous growth of other chronic conditions and comorbidities” that will “likely lead to expansion of the high-risk PCI (percutaneous coronary intervention) patient population.”

With the cost of cardiovascular care escalating, hospitals and physicians are looking for new ways to deal with expensive patient populations. The Impella 2.5® and Impella CP® heart pumps are the only hemodynamic support proven safe and effective for use in elective and urgent high risk percutaneous coronary interventions (HRPCI).

There are many potential benefits for hospitals that develop an HRPCI program with Impella®:

- Opportunity to treat patients previously turned down for high risk PCI
- Reduced adverse events
- Improvement in quality of life for patients
- Reduced length of stay
- Lower rates of repeat revascularization and related admissions

Cost-effectiveness of the Impella 2.5® and Impella CP® devices have been demonstrated through a randomized controlled trial, all-payer population based studies, and a systemic review of reduced length of stay. Study observations include fewer readmissions, less days in the hospital, and a better quality of life through reduced heart failure symptoms.
Protected PCI with Impella® heart pump programs can help hospitals meet clinical needs and business challenges

Cardiovascular conditions remain a substantial contributor to the volumes and the cost of readmissions. In 2010, over $17 billion was estimated as the cost to the American public for hospital readmissions for Medicare beneficiaries. Cardiovascular disease is the leading cause of hospital readmissions among both Medicare beneficiaries and those with commercial insurance. Five of the top seven conditions most commonly attributed to readmissions are cardiovascular in nature. Public reporting and financial penalties for readmissions have hospitals struggling to find a balance between cost and quality.

Adding a Protected PCI with Impella Program to the platform of cardiovascular services offered at a hospital may have a positive effect on the clinical needs and business challenges that hospitals are facing. Protected PCI may allow physicians to perform a more complete revascularization and attract new patient volumes. More information regarding Protected PCI with Impella can be found in Abiomed’s Protected PCI with Impella Clinical Dossier.

Additionally, Impella 2.5®, Impella CP®, Impella 5.0®, and Impella LD® heart pumps are FDA indicated to provide treatment of ongoing cardiogenic shock. In this setting, the Impella® heart pumps have the ability to stabilize the patient’s hemodynamics, unload the left ventricle, perfuse the end organs, and allow for recovery of the native heart. Impella® devices have also been proven to be cost effective through reduction in length of stay, readmissions, and overall costs compared with alternative treatment. This latest approval adds to the prior FDA indication of Impella® devices for elective and urgent high-risk PCI, or Protected PCI.

Impella® devices have been determined to be one of the most cost effective treatments in cardiogenic shock. Maini, et al. concluded that in addition to reduction in length of stay (LOS), patients treated with Impella® devices had improved survival with reduced cost. A systemic review of cost effectiveness studies also observed a reduction in LOS across multiple patient populations.
More information regarding the use of Impella® heart pumps in the setting of cardiogenic shock can be found in Abiomed’s Clinical Dossier Cardiogenic Shock therapy with Impella®.

The purpose of this resource guide is to assist cardiovascular leaders in establishing and strengthening the use of Impella® heart pumps with a program focus. For more information regarding how to establish or strengthen your program, visit the Abiomed website at www.Abiomed.com.
Programs addressing the unique needs of Protected PCI patients and those focusing on improving outcomes in Cardiogenic Shock have demonstrated the need for programmatic structure and ownership. Successful Impella® heart pump programs share the best practice of securing strong buy-in from a multi-disciplinary group of key stakeholders at all development milestones. Having a multi-disciplinary team that is vested in the success of the program will be the foundation for the successful growth of the program. Without buy-in from this multi-disciplinary group, programs can struggle throughout establishment and will not meet growth goals or outcomes improvement potential. Many hospitals find that having a “kick-off meeting” is a great way to generate excitement for the program and begin working through potential roadblocks. This group will implement and maintain these key components of successful programs:

- Structure and ownership
- Algorithm development and implementation
- Protocols and tools
- Initial and continuous training initiatives
- Quality improvement metrics
- Public awareness
- Designating a Protected PCI Coordinator and Outreach education
- Optimized economics

Each of these key components is illustrated in Figure 2.

The development of this multi-disciplinary group follows the concept of care team creation. Creation of care teams to deliver high-quality, cost-effective cardiovascular care has gained support over the last few years. Generally, the following stakeholders have a critical role in...
defining the success of an Impella® heart pump program:

- Administration (CEO, CMO, CFO, CNO, VPs as appropriate)
- Cardiology Data Abstractors (ACC/NCDR and STS)
- Cardiology Stakeholders (General Cardiologist, Interventional Cardiologist, Heart Failure, etc.)
- Catheterization Laboratory leadership
- Coding and Billing Leadership/financial team
- Echosonography
- Heart failure
- Hospitalist
- Intensivist
- Marketing
- Nursing leadership from care units (ICU, CCU)
- Pharmacy
- Quality Assurance
- Surgery (Cardiothoracic or vascular surgery as appropriate)

There are many other stakeholders that can play key roles to the program’s success. While involving these stakeholders in the core establishment meetings may not be required; their expertise will be crucial as the program expands. An example of those individuals is listed here:

- Admissions
- Anesthesia
- Biomedical Engineering
- Case Management
- Emergency Department leadership
- Emergency Department Physicians
- Electronic Medical Record Leadership
- Information technology
- Laboratory
- Perfusion
- Supply Management
- Transfer Center

The multi-disciplinary group will lead a strong collaborative relationship between surgery and cardiology, developing a “heart team” approach. The “heart team” approach will align the caregivers of the cardiovascular patient allowing for the patient to be cared for by those with the training and skills needed to provide high-quality, coordinated care that is specific to the patient’s clinical needs and circumstances.11

Once the multi-disciplinary group has been established, the group should agree on the goals for the Impella® program. With all of the disciplines invested in the goals of the program, a program owner must be selected. Hospitals vary in who they appoint to this position. Program ownership may be designated to a physician, a clinical nurse specialist, a nurse manager, or another leader. The role of the owner is to facilitate the development of the program and ensure continuous collaboration between all stakeholders. Whether your hospital is focusing on Protected PCI with Impella®, a Heart Recovery Program targeting outcomes in Cardiogenic Shock, or both, the program owner will need the empowerment to make decisions that impact the program’s success.
Some hospitals have elected to appoint a Protected PCI Coordinator to fill the role of the program owner. In The Advisory Board Company’s Guide to Protected PCI in High-Risk Cardiovascular Patients, hospitals participating in their research concluded that “a coordinator helps manage” the care pathway of the high-risk patient. Many successful programs have determined that using a “non-physician coordinator or navigator helps bring all the pieces of the high-risk PCI program together.” This dedicated coordinator becomes an integral part of the program – being the champion of the program’s vision, mission, goals and quality measures. When programs have a designated coordinator, the coordinator ensures that the patient selection algorithm is consistently applied to all patients as well as facilitating the patient’s experience to minimize delays in care and improve length of stay. Other roles of the coordinator include:

- Coordinating the Heart Team evaluation of patients when appropriate
- Providing education to the patient and their family regarding the procedure
- Serving as the patient’s primary contact throughout the procedure
- Coordinating communication to general cardiologists, internal medicine and other first line caregivers
- Coordinating follow up
- Leading After Action Reviews (discussed on page 11)
- Providing community education
- Collecting outcome data (including length of stay)

A sample job description and competency checklist for a “Protected PCI Program Coordinator” can be found in Appendix A. In addition, a sample Protected PCI Program consult form is included to assist coordinators with patient identification.

Algorithm Development and Implementation

In order to provide consistent care to all high-risk complex coronary artery disease patients, the multi-disciplinary group must develop and fully implement an algorithm for patient selection. Sample algorithms are included in Appendix B. The purpose of the selection algorithm is “to guide interventional cardiologist in clinical decision making for choosing mechanical circulatory support devices in patients undergoing percutaneous coronary intervention with high risk features or cardiogenic shock.”

Once the multi-disciplinary team has selected an owner/coordinator, the team must develop and implement an algorithm for patient selection. The algorithm does not replace the role of the heart team but provides a guideline that summarizes the agreement of the team on which patients are appropriate for support once the decision to perform a high risk PCI has been reached. The team should agree that the algorithm will be applied to all patients who meet the criteria and that cases will be reviewed for appropriate use as well as those to which the algorithm was not followed. Cardiology and Cardiothoracic surgery must reach a consensus before the algorithm is presented for final approval.

There are several steps to developing and implementing a Protected PCI algorithm:

1. Set a goal date for full approval of the algorithm in accordance with hospital policy. Using this date as the completion date, set key milestone dates leading up to the project end date. Everyone on the team must be held accountable to meeting the goal date for approval and implementation.

2. Review Abiomed’s Clinical Dossier Protected PCI with Impella and other research based publications found in the reference section of the dossier.
3. Review the sample algorithms attached in Appendix B.

4. Using the sample algorithms as a guide, create your hospital’s algorithm including inclusion and exclusion criteria.

5. Determine how compliance with the algorithm will be managed – weekly, monthly, quarterly? Who is responsible for reporting that a patient was not managed according to the protocol?

6. Once the team has reached a consensus, the algorithm may be submitted and approved as per hospital policy.

7. Upon approval of the algorithm, distribute to all staff and provide education regarding the use of the algorithm. Some hospitals post their algorithm in the catheterization lab so that all of the staff can regularly view it. Other hospitals may choose to implement more proactive actions such as using it as a part of the “Time Out” process to determine if the patient is getting the correct procedure based upon the inclusion criteria.

This process can also be followed to develop and implement a cardiogenic shock treatment protocol using the clinical dossier for cardiogenic shock. The Impella Best Practices in AMI Cardiogenic Shock Algorithm is found in Appendix C. The Detroit Cardiogenic Shock (Detroit CSI) Algorithm can be found in Appendix D. This algorithm represents a 5-hospital collaborative to improve cardiogenic shock outcomes.

Protocols and Tools

In order to provide guidance for establishment of hospital protocols and tools for patient management, Abiomed, Inc. provides the Impella® Program Protocols & Tools. This guidebook includes:

- Impella Heart Pump Clinical Protocols
- Protocol Implementation Tools
- Skills Checklists
- Supply Lists
- Other program resources available through Abiomed

Abiomed, Inc. Program Protocols & Tools can be viewed on www.protectedpci.com or obtained by requesting a form from your local Abiomed representative.

Initial and Continuous Training Initiatives

Continuous training is a hallmark of a successful program. The implementation and training initiatives can be facilitated by the program coordinator. Site launch and training efforts begin at the “kick-off” meeting described in the “Structure and Ownership” discussion. In best practice centers, the training and education efforts are continuous for all staff that interacts with the Impella® heart pump patient. The following topics are just a few of the training topics that all staff should receive on a frequent basis:

- After Action Reviews (AAR)
- Alarms
- Algorithms
- Appropriate patient selection for Protected PCI and AMI Cardiogenic Shock
• Appropriate placement
• Hemodynamics of Impella®
• How the Impella® catheters work
• Patient education
• Patient management
• Protocols
• Purge cassette maintenance
• Removal process
• Set-up process
• Trouble shooting

In addition, a sample Impella® Program Training Schedule can be found in Appendix E.

Abiomed, Inc., the manufacturer of the Impella® heart pumps, offers a thorough training program for both physicians and hospital staff. Training covers the full spectrum of therapy, from an overview of the technology, Automated Impella Controller (AIC) and system set-up and insertion, through patient management topics such as appropriate patient selection. Abiomed offers numerous training avenues, including:

• 24/7 clinical and technology telephone support through the Emergency Clinical Support Hotline (1-800-422-8666)
• Automated Impella Controller (AIC)
• Clinical support and on site, hands-on customer training
• Impella Clinical Expert (ICE) training programs
• Impella® app for iPhone
• Masters Programs
• Mobile Learning Labs (MLL)
• Print and web-based educational materials
• Physician certification
• Quick skills videos
• Reimbursement Hotline (1-877-256-0861)

In addition to taking advantage of training offerings, hospitals have built successful programs though initiatives such as:

• Designating a “physician champion”
• Implementing After Action Reviews (AAR)
• Identifying and training more experienced users
• Implementing comprehensive general product training
• Leveraging the Heart Team approach
• Multi-disciplinary approach to training
• Outreach education to general cardiologists, internal medicine, and other first line caregivers

**Designating a “Physician Champion”**

A “physician champion” is a visionary for the program. Their role is to champion the need for treating and identifying the Protected PCI patient population and the improvement of outcomes in cardiogenic shock. In some hospitals, a cardiologist may serve as the champion for one program and a surgeon for the other. These physicians assist with appropriate patient selection, training and live cases, protocol adoption and quality measurement. These physicians also navigate inevitable roadblocks that arise as Impella® programs are being developed.
Leveraging the Heart Team Approach

Having a heart team approach is important because it allows collaboration between cardiology and surgery which is recommended for evaluating patients for PCI and CABG. In fact, the choice of the appropriate treatment, PCI vs. CABG by a multi-disciplinary “Heart Team” is a Class I Guideline.\(^\text{13}\)

For the Protected PCI patient, many hospitals have found that designating a specific time or week day for complex cases facilitates program growth and allows the Heart Team to dedicate time for the procedure. Dedication of the lab on a certain day can also encourage consistency of care for this patient population and allow for staffing adjustments to provide skilled staff as well as learning opportunities for others.

Identifying and Training More Experienced Users

All of the hospitals that have implemented and maintained successful programs identify “super users”. These “super users” are members of their own staff who are enthusiastic about learning new technologies and have the ability to not only teach but influence those around them towards adopting new technology. Select those in the catheterization laboratory and Intensive Care Units who take an early and focused interest in the Impella\(^\text{®}\) technology. These “Super Users” will quickly become experts and serve as trainers for other staff members in the hospital. In addition, a staff member who is drawn to technology may choose to assist with implementation and updating the Impella\(^\text{®}\) heart pump related policies and procedures. These employees may lead in competency evaluations and educate staff as advances in the technology occur. As this employee gains more experience, they will also serve as a resource for staff in complex situations. This scenario results in a win-win situation for the employee and the program.\(^\text{13}\) The “super users” influence other users creating an atmosphere of peer preceptors to sustain the continued educational needs of new and existing staff.

Implementation of Comprehensive General Product Training

Abiomed offers the following standard training for users:

- General training on the Impella AIC and catheters
- Hands-on training for small groups of 3 to 4 physicians and staff
- Proctored case training facilitated by an Abiomed Clinical Specialist conducted on site for physicians and staff during actual cases
- Ongoing refresher training depending on usage patterns

General product training is the bedrock of Impella\(^\text{®}\) programs, laying the foundation for the system and its advantages and benefits as well as explaining the basic operation and set-up of the system. However, it is important to layer hands-on, often one-on-one and extended team on-site training. In addition to the initial general training foundation, it is also important to provide online testing with a specific focus on placement in the ventricle, care during use, troubleshooting alarms and device removal. Physicians and support personnel significantly benefit from education regarding appropriate indications, appropriate patient selection, insertion techniques, and device management and removal techniques. Focusing time on troubleshooting during an actual Impella\(^\text{®}\) case as well as in the ICU setting will build confidence for the caregivers. Depending on usage patterns, ongoing refresher training can also help maintain a high level of proficiency among physicians and staff.

In addition, there are more advanced training opportunities available at a variety of locations such as:

- Mobile Learning Lab (MLL) – your Abiomed representative can provide your hospital with information regarding locations and dates for the MLL in your area. The MLL is a mobile education center that offers hand-on simulated training for all of the healthcare team members participating in the care of the Impella patient.
• Impella Clinical Expert programs (ICE) – a comprehensive eight hour training course offering both Continuing Education Units (CEUs) and Continuing Education Recognition Points (CERPs) to participants. These programs are offered regionally and can be coordinated through the Abiomed representative at your facility
• Masters Training Programs
• Impella App – the Impella app can be downloaded to iPhones and offers immediate assistance for the most common user questions

Multi-Disciplinary Approach to Training

A multi-disciplinary approach to training is important due to the scope of procedural and patient management issues. Depending on the insertion site and the type of Impella® heart pump inserted, the insertion technique will differ. Impella® heart pumps can be inserted via one of several endovascular percutaneous or peripheral approaches. Femoral and subclavian artery access points require both surgical and catheter-based skills, making Impella® insertion a truly hybrid procedure. Femoral angiography is required to document sufficient vascular caliber and lack of severe stenosis or tortuosity before device placement. The sternal approach for the Impella LD® requires an open surgical approach. Accurate Impella® placement requires intraoperative fluoroscopy and transesophageal echocardiography (TEE). Impella® is used in many different environments (catheterization labs, operating rooms, hybrid rooms) and under different patient conditions (both intubated and non-intubated). With so many options, it is easy to see why a multi-disciplinary approach to Impella® training is vital.

After Action Reviews (AAR)

After Action Reviews (AAR) are a valuable tool used to immediately review patient care. This process has been used by many different entities to assess the results of actions. AARs are intended to be completed at the end of a procedure by all of those who participated in the planning and delivery of the procedure. The purpose is to create a culture of learning.

After the procedure, the AAR process requires that the participants answer the following questions:

1. What was the plan?
2. What really happened?
3. What did we learn?
4. Who needs to know?

All participants should be able to freely state their perception of the answers to the above questions. The results should be used to influence care for future procedures. A sample AAR can be found in Appendix F on page 23.
References


Appendix A: The Protected PCI Coordinator

Job Title: Protected PCI Coordinator/Outreach Coordinator
Department: Cardiovascular

Job Responsibilities:

The Protected PCI Program Coordinator/Outreach Coordinator will be responsible for the development and implementation of the multi-disciplinary program. The Coordinator will take a lead role in the overall function of the Protected PCI Team, understanding and articulating the mission, vision, goals and strategies for the program and patients served. The primary role will be centered on appropriate patient identification and selection using heart team approach and algorithm to provide consistent care and improve outcomes. Additional duties outside of coordination of patient identification and selection include outreach to internal and external referral sources and community education.

Principal Duties and Responsibilities

Clinical Duties

- Facilitate physician decisions based on patient selection algorithm
- Development and implementation of Protected PCI algorithm in collaboration with multi-disciplinary heart team
- Development of patient care protocols and other documents required to facilitate standardization of care
- Coordinate multi-disciplinary meetings
- Conduct/Collect data from After Action Reviews (AAR) for all patients
- Facilitate communication between inpatient departments and outpatient Navigators for continuous patient care

Outreach Duties

- Develop and implement outreach materials for general cardiologists, internal medicine, and other first line caregivers
- Provide outreach education to internal and external referral sources
- Facilitate communication to referral physicians throughout plan of care

Patient Centered Duties

- Primary resource for patients and families
- Facilitates patient throughput to enhance outcomes and patient experience
- Improve patient outcomes through quality improvement activities
- Provide training/coordinate training for hospital staff based on needs

Educational Duties

- Develop Department-specific educational materials
- Develop patient and family educational materials
- Facilitate staff education programs as needed

Research Related Duties

- Support research Coordinator in data collection for registries and studies related to Protected PCI
- Identify educational opportunities for staff to ensure proper documentation

Requirements:

- RN recommended or other healthcare professional with cardiovascular experience
- Experience in outreach/marketing recommended
- Strong organizational and communication skills

This job description is intended to describe the general nature and level of the work being performed by employees in this job. It is not intended to be a complete list of responsibilities, duties and skills required for this job classification.
# Protected PCI Program Coordinator/Outreach Coordinator

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>COMPLETED / NOT COMPLETED</th>
<th>COMPLETION DATE</th>
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<tbody>
<tr>
<td>Develop, implement and maintain Algorithm to identify appropriate candidates for Protected PCI procedures</td>
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<tr>
<td>Develop and implement educational outreach programs for internal and external physicians around Protected PCI as a treatment option</td>
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<td>Ensures follow-up communication to referral physicians</td>
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<tr>
<td>Conducts/compiles AARs (After Action Reviews) on all patients</td>
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<tr>
<td>Develops, implements and maintains protocols for Protected PCI Patient management</td>
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<tr>
<td>Conducts initial evaluation of potential candidate for Protected PCI procedure and identifies clinical criteria supporting or excluding use</td>
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<tr>
<td>Coordinates multi-disciplinary meetings regarding patient selection, care, outcomes and process improvement</td>
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<td>Collaborates with physicians to ensure timely treatment of patients</td>
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<td>Facilitate communication with appropriate caregivers to ensure continuation of Patient Care Pathway</td>
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<tr>
<td>Develops and maintains Scope of Service for Protected PCI Program</td>
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<tr>
<td>Full understanding of FDA approved indications and contraindications for each Impella® device</td>
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<tr>
<td>Develop and maintain electronic database for Protected PCI Patient population</td>
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<tr>
<td>Develops, coordinates and provides department-specific training programs for Impella® technology and Protected PCI Program</td>
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<tr>
<td>Develop and implement training program for EMS providers, on Impella® technology, to include transfer of Impella® supported Patients</td>
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<tr>
<td>Develop and implement educational materials for Patients and Families around Protected PCI and Impella® technology</td>
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<tr>
<td>Act as primary resource for Cardiac Catheterization Lab staff, Operating Room staff, and ICU staff</td>
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<tr>
<td>Provide education to Patients and Families around Protected PCI procedure and Impella® technology</td>
<td></td>
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</tr>
<tr>
<td>Function as primary contact for Patients and Families throughout hospitalization</td>
<td></td>
<td></td>
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<tr>
<td>Act as primary resource for Cardiac Catheterization Lab staff, Operating Room staff, ICU staff</td>
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<tr>
<td>Ensure that Quality Initiatives are implemented and results reported to Protected PCI Team</td>
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<tr>
<td>Complies with Hospital policies regarding confidentiality</td>
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</tbody>
</table>

This sample job specific competency is intended to describe the general nature and level of the work being performed by employees in this role. It is not intended to be a complete list of responsibilities, duties and skills required for this job classification.
To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit:

www.protectedpci.com/hcp/information/isl
www.cardiogenicshock.com/information/isl
Appendix B: Sample Protected PCI Protocols

A Practical Approach to Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention

PERSPECTIVES

WHAT IS KNOWN? Mechanical circulatory support devices have been used for decades to support patients in cardiogenic shock or patients undergoing high-risk percutaneous coronary intervention. Newer devices offer a greater level of hemodynamic support, but device selection can often be challenging.

WHAT IS NEW? An algorithm was created to guide interventional cardiologists in clinical decision making for choosing mechanical circulatory support devices in patients undergoing percutaneous coronary intervention with high risk features or cardiogenic shock.

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: www.protectedpci.com/hcp/information/isi and www.cardiogenicshock.com/information/isi. Transcaval access is an off label technique for implanting Impella. Its safety and effectiveness have not been demonstrated.
Left Ventricular Mechanical Circulatory Support Device (MCS) Decision Tree Before Elective CTO and Complex PCI

Elective CTO or Complex PCI

Patients at Risk of Hemodynamic Collapse based on physician assessment of the following:

- Advanced structural heart disease in the left heart (MR, AI, AS)
- Unstable rhythm disturbances despite medical therapy
- Advanced age patients (>75 years)
- Renal failure
- Active symptoms of heart failure

- Elevated PCWP or LVEDP
- Cardiac Index < 2.2 L/min/m²
- Cardiac Power (MAP x CO/451) < 0.6

- Multivessel PCI
  - PCI on the last available conduit
  - CTO PCI using retrograde technique through the last available conduit
  - CTO PCI of the RCA or the LCX using retrograde access via LIMA to LAD
Protected PCI Clinical Decision Plan — VA North Texas Healthcare System

- Multivessel
- Left Main
- Calcification
- Tortuosity
- Thrombus
- Diffuse Disease
- Last Remaining Vessel

PCI

Revascularization

YES

Diagnosis: High Risk Patient

Treatment Decision

Anatomy

Clinical Presentation

Hemodynamics

- Low EF
- Hypotension/shock

PCI

Hemodynamic Support Indicated?

No

Conventional PCI

Yes

Protected PCI with Impella® device

Surgical Ineligibility
- Hemodynamically stable, LVEF <35%
- Complex CAD with comorbidities
- FDA approved indications
- Per Guidelines

— GOAL —
More Complete Revascularization
Protected PCI at University Hospitals

LVEF < 35%
- Unprotected Left Main (ULM)
- Multi-vessel Intervention
- Atherectomy of Large Vessel

Pre-Close with 2 Proglides

Impella 2.5/CP (3.5)

PCI

Good result (anticipated ~95%)
- Cath Lab Rapid Wean
- Complete Proglide Closure

Suboptimal result (anticipated ~5%)
- <TIMI 3 flow in a target vessel
- Untreated dissection
- Persistent hypotension
- Persistent chest pain with EKG change
- Swan Ganz in Cath Lab
- Continued Support in CCU

Anatomical & Procedural Risk (Independent of EF)
- PCI on last available conduit
- CTO PCI using retrograde technique through the last available conduit
- CTO PCI using retrograde access via LIMA to LAD
- Atherectomy of ULM
- Distal LM with proximal LAD and Cx (Medina 1, 1, 1)

February 2017
Appendix C: Impella® Best Practices in AMI Cardiogenic Shock

Impella® Best Practices in AMI Cardiogenic Shock

Identify\(^{10, 15, 16}\) (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\(^{23-25}\)
  - Reduce Inotropes/Pressors\(^{27,28}\)

Complete Revascularization
- PCI Guidelines based in Cardiogenic Shock\(^{26,30}\)

Assess for Myocardial Recovery
(Weaning and Transfer Protocols)
- Cardiogenic etiology evaluation
  - EKG (STEMI / NSTEMI)
  - Echocardiography\(^{17}\)
  - If available, PA Catheter\(^{26}\)
  - Cardiac Output, CPO, CI, PCWP, Svo\(_2\)\(^{18-20}\)

Myocardial Recovery\(^{21, 31}\)
- ↑ Cardiac Output
- ↑ Cardiac Power Output
- ↑ Urine Output
- ↑ Lactate
- ↓ Inotropes

No Recovery Escalate (& Ambulate) Or Transfer\(^{17}\)
- Ongoing Left heart failure
- Assess for Right heart failure\(^{22}\)


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\(^{10}\) Identify criteria consistent with HEMORRHAGE, H счета of the most suitable strategies to achieve hemostasis, ensuring patient safety and minimizing complications.

\(^{15}\) Hemostasis

\(^{16}\) Establish the presence of bleeding, and consider the use of appropriate interventions to control or prevent further bleeding.

\(^{18}\) Impella® Support

\(^{23}\) PCI Guidelines

\(^{25}\) Pre-PCI

\(^{26}\) PA Catheter

\(^{27}\) Reduce Inotropes

\(^{28}\) Pressors

\(^{29}\) Cardiogenic Shock

\(^{30}\) Guidelines

\(^{31}\) Myocardial Recovery
**DETROIT CARDIOGENIC SHOCK INITIATIVE**

**DETOIT CARDIOGENIC SHOCK INITIATIVE ALGORITHM**

**INCLUSION CRITERIA**
- Acute Myocardial Infarction
  - Ischemic Symptoms
  - EKG and/or biomarker evidence of AMI (STEMI or NSTEMI)
- Cardiogenic Shock
  - Hypotension (<90/60) or the need for vasopressors or inotropes to maintain systolic blood pressure >90
  - Evidence of end-organ hypoperfusion (cool extremities, oliguria, lactic acidosis)

**EXCLUSION CRITERIA**
- Evidence of Anoxic Brain Injury
- Unwitnessed out of hospital cardiac arrest or any cardiac arrest in which ROSC is not achieved in 30 minutes
- IABP placed prior to Impella
- Septic, anaphylactic, hemorrhagic, and neurologic causes of shock
- Non-ischemic causes of shock/hypotension (Pulmonary Embolism, Pneumothorax, Myocarditis, Tamponade, etc.)
- Active Bleeding
- Recent major surgery
- Mechanical Complications of AMI
- Known left ventricular thrombus
- Patient who did not receive revascularization
- Mechanical aortic valve

**ACCESS & SUPPORT**
- Obtain femoral arterial access (via direct visualization with use of ultrasound and fluoroscopy)
- Obtain venous access (Femoral or Internal Jugular)
- Obtain either Fick calculated cardiac index or LVEDP

**Coronary Angiography & PCI**
- Attempt to provide TIMI III flow in all major epicardial vessels other than CTO
- If unable to obtain TIMI III flow, consider administration of intra-coronary vasodilators

**Perform Post-PCI Hemodynamic Calculations**
1. Cardiac Power Output (CPO): \( \frac{MAP \times CO}{451} \)
2. Pulmonary Artery Pulsatility Index (PAPI): \( \frac{sPAP - dPAP}{RA} \)

**Wean OFF Vasopressors and Inotropes**
If CPO >0.6 and PAPI >0.9, operators should wean vasopressors and inotropes and determine if Impella can be weaned and removed in the Cath Lab or left in place with transfer to ICU.

**Escalation of Support**
If CPO remains <0.6 operators should consider the following options:
- PAPI is <0.9 consider right sided hemodynamic support
- PAPI >0.9 consideration for additional hemodynamic support
- Local practice patterns should dictate the next step:
  - Placement of more robust MCS device(s)
  - Transfer to LVAD/Transplant center
If CPO is >0.6 and PAPI <0.9 consider providing right sided hemodynamic support if clinical suspicion for RV dysfunction/failure

**Vascular Assessment**
- Prior to discharge from the Cath Lab, a detailed vascular exam should be performed including femoral angiogram and Doppler assessment of the affected limb.
- If indicated, external bypass should be performed.

**ICU Care**
- Daily hemodynamic assessments should be performed, including detailed vascular assessment
- Monitor for signs of hemolysis and adjust Impella position as indicated

**Device Weaning**
Impella should only be considered for explantation once the following criteria are met:
- Weaning off from all inotropes and vasopressors
- CPO >0.6, and PAPI > 0.9

**Bridge to Decision**
Patients who do not regain myocardial recovery within 3-5 days, as clinically indicated, should be transferred to an LVAD/Transplant center. If patients are not candidates, palliative care options should be considered.

**QUALITY MEASURES**
- Door to Support Time < 90 minutes
- Establish TIMI III Flow
- Wean off Vasopressors & Inotropes
- Maintain CPO >0.6 W
- Improve survival to discharge to >80%

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: [www.protectedpci.com/hcp/information/isi](http://www.protectedpci.com/hcp/information/isi) and [www.cardiogenicshock.com/information/isi](http://www.cardiogenicshock.com/information/isi).

Impella heart pumps are approved for use for up to four days so please note that the 3-5 days, as indicated in the graphic above, is an off-label technique. Its safety and effectiveness have not been demonstrated.
## Example Impella® Program Training Schedule

**July 2017**

<table>
<thead>
<tr>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
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<td><strong>Online Training – Cath Lab, ICU &amp; Physician (optional)</strong></td>
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<td><strong>Cath Lab MD training</strong></td>
<td><strong>Cath Lab MD training</strong></td>
<td><strong>Cath Lab MD training</strong></td>
<td><strong>ICU Super User training</strong></td>
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### AAR Template

<table>
<thead>
<tr>
<th>What was the plan?</th>
<th>What really happened?</th>
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</thead>
<tbody>
<tr>
<td>Perform more complete revascularization</td>
<td>EF lower than expected pre procedure (EF 30%)- Pt not identified early</td>
</tr>
<tr>
<td>Use invasive hemodynamic monitoring (EF 35%)</td>
<td>Impella placed late in response to low MAP following balloon inflation</td>
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<tr>
<td>Unload LV with Impella if needed</td>
<td>Complete revascularization procedure performed after support implemented</td>
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<tr>
<td>Minimize exposure to toxic inotropic medications</td>
<td>Patient remained on support post procedure</td>
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<td>Transfer to ICU on support- ICU RN had to be called in</td>
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</table>

<table>
<thead>
<tr>
<th>What did we learn?</th>
<th>Who else needs to know?</th>
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</thead>
<tbody>
<tr>
<td>Protocol in place but not consistently followed</td>
<td>CV Administration- standard use of protocol for pt selection</td>
</tr>
<tr>
<td>Senior physicians don’t have buy-in for protocol</td>
<td>ICU leadership- education of ICU staff</td>
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<tr>
<td>Staff unaware of protocol</td>
<td>Heart Team Committee – review of protocol and implementation of protocol standardization</td>
</tr>
<tr>
<td>Not all ICU nurses trained for Impella patients</td>
<td>Cath Lab leadership – empowerment of Cath Lab staff for protocol implementation</td>
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For additional tools and resources to help with the building of your Impella program, please visit [www.protectedpci.com](http://www.protectedpci.com)

Protectedpci.com is Abiomed’s online Protected PCI community and is the largest source of education and reference materials on pVADs and the Impella® platform.
Clinical support
24 hours per day,
7 days a week:
1-800-422-8666 (US)
+49 (0) 1805 2246633 (EU)

ABIOMED, Inc.
22 Cherry Hill Drive, Danvers, MA 01923 USA
Voice: 1-978-777-5410
Facsimile: 1-978-777-8411
Email: marketing@abiomed.com

ABIOMED Europe GmbH
Neuenhofer Weg 3, 52074 Aachen, Germany
Voice: +49 (241) 8860-0
Facsimile: +49 (241) 8860-111
Email: europe@abiomed.com

Reimbursement Assistance
Reimbursement Hotline: 1-877-256-0861
Monday through Friday, 8 am - 5 pm, CT
Email: reimbursement@abiomed.com