The Impella heart pump is an intravascular microaxial blood pump that supports a patient’s circulatory system.

- Inserted percutaneously through the femoral artery
- Inlet directly unloads the left ventricle reducing ventricular work for up to 4 days for indications including support during high-risk PCI and support post AMI CGS (refer to Indications on the back of this document)
- Heart pump provides peak flow up to of 4.3 L/min for systemic perfusion
- Outlet located in the ascending aorta supports coronary perfusion
- Enables repositioning in the ICU without imaging*

Cannula:
Polyurethane coated nitinol with a 145-degree angle

EasyGuide Lumen:
Red loading lumen to ease guidewire loading

Position Sensor:
Optical pressure sensor located immediately distal to the outlet, provides a pressure reading indicating aortic pressure only when both the outlet and sensor are located within the aorta

Catheter Shaft:
Polyurethane catheter with nitinol backbone and triple internal lumens for pressure, purge and electrical signal

Repositioning Unit:
Graduated shaft from 9 Fr to 13 Fr with StatLock® compatible suture pads and anti-contamination sleeve. Guidewire reaccess sheath maintains guidewire access to arteriotomy 13 Fr section is 10cm in length

Red Impella Plug:
Connections - 1 luer connection for purge fluid, 1 electrical connection direct to Automated Impella® Controller
Electronics - electronic memory for retention of operating parameters

Specifications

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<th>Impella CP Optical Heart Pump</th>
<th>Catheter Shaft</th>
<th>StatLock® Suture Pad</th>
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<tr>
<td>Maximum Flow</td>
<td>4.3L/min</td>
<td>9 Fr Catheter, 14 Fr pump</td>
<td>3 Fr Pigtail</td>
<td>92-98cm</td>
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<tr>
<td>Maximum Mean</td>
<td>3.7 L/min</td>
<td>Blood Inlet</td>
<td>Radiopaque Marker</td>
<td>46,000 rpm</td>
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<tr>
<td>Speed Range</td>
<td>0 to 46,000 rpm</td>
<td>Blood Outlet</td>
<td>Optical Sensor</td>
<td>Diameter: 9 Fr catheter, 14 Fr pump</td>
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<tr>
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<td>92-98cm</td>
<td>6 Fr Pigtail</td>
<td>9 Fr Delivery Catheter</td>
<td>Length: 92-98cm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For additional information about flow rates see the Instructions For Use manual.
The Impella 2.5®, Impella CP®, and the Impella CP® with SmartAssist®, Impella 5.0® and Impella LD® Catheters, in conjunction with the Automated Impella Controller (collectively, “Impella® System”) 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.

High-Risk PCI

The Impella 2.5®, the Impella CP®, and the Impella CP® with SmartAssist® 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, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, the Impella CP, and the Impella CP® with SmartAssist® 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®, the Impella CP®, and the Impella CP® with SmartAssist®, 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, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 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 or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis 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, and the Impella CP with SmartAssist, Impella 5.0 and Impella LD catheters 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 ≥ ++); 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. Learn more visit: www.abiomed.com/important-safety-information