Data Sheet

Impella 5.5™ with SmartAssist®

A minimally invasive heart pump delivering peak flows >6 L/min of full forward flow, enabling heart recovery.

- The Impella 5.5 with SmartAssist can be inserted through the axillary artery or anterior aorta and across the valve and into the left ventricle
- Inlet directly unloads the left ventricle reducing ventricular work for up to 14 days for indications including support during cardiogenic shock
- Heart pump provides peak flow >6 L/min for systemic perfusion
- Outlet located in the ascending aorta supports coronary perfusion
- Enables repositioning in the ICU without imaging*

* For ventricularized pumps only

Specifications

Cannula:
Polyurethane coated nitinol with a 145-degree angle. Rigid cannula improves deliverability

Motor Housing:
A decrease in motor housing size allows for ease of vascular navigation around the innominate artery

Catheter Shaft:
Polyurethane catheter with reinforced steel coil and triple internal lumens for pressure, purge and electrical signal

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

Blue Suture Hub:
Designed to be inserted into a 10mm graft with StatLock® compatible suture pads and anti-contamination sleeve

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

Overview

1. Inlet
2. Cannula
3. Outlet
4. Motor Housing
5. Catheter Shaft
6. Blue Suture Hub
7. Red Impella Plug

Maximum Flow: >6 L/min
Maximum Mean: 5.2 L/min
Speed Range: 0 to 33,000 rpm
Diameter: 9 Fr Catheter, 21 Fr pump

For additional information about flow rates see the Instructions For Use manual.
Impella 5.5™ with SmartAssist®

Accessories

**Impella 5.5 Kit**
Part number: 0550-0008
- Impella Catheter (0550-0007)
- Purge Cassette (0043-0001)
- Axillary Insertion Kit (0052-3009)
- 0.018” x 260cm placement guidewire (0052-3005)

**Automated Impella Controller**
Part number: 0042-0010-US
The controller provides an interface for monitoring and controlling the function of all Impella catheters.
- 10.4” color display for easy viewing
- Mounts to Controller Cart (not shown) for transport within hospital
- 60 minutes of battery back-up power for mobile transport

**Axillary Insertion kit**
Part number: 0052-3009
Vascular access kit used for axillary insertion sheath of the Impella catheter.
- 2 Graft locks
- 23 Fr x 6 cm Peel-away introducer with hemostatic valve
- 8 Fr Silicone-coated dilator

**0.018”x 260cm Placement Guidewire**
Part number: 0052-3005
Guidewire with a radiopaque, shapable tip used for placement of Impella catheter into left ventricle.

**Purge Cassette**
Single Package: 0043-0002
5 Package: 0043-0003
The purge cassette delivers rinsing fluid to the Impella catheter. The purge fluid flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor.

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**Cardiogenic Shock**
The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, Impella 5.5™ with SmartAssist® 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, Impella 5.5 with SmartAssist 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, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist 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 cardiopulmonary 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.abiomed.com/important-safety-information](http://www.abiomed.com/important-safety-information) to learn more.