Peak Flows up to: 6 L/min
Maximum Mean Flow: 5.5 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.

StatLock is a registered trademark of C. R. Bard, Inc

Data Sheet
Impella 5.5® with SmartAssist®

A minimally invasive heart pump that delivers full support, allowing the heart to rest and enabling heart recovery.

- Inserted via the axillary artery, through the ascending aorta, and across the aortic valve 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 full hemodynamic support with maximum unloading
- 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:
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, anti-contamination sleeve, and catheter anchor

New catheter lock always locked

Other Features:
New integrated purge filter unit improves patient management and mobility

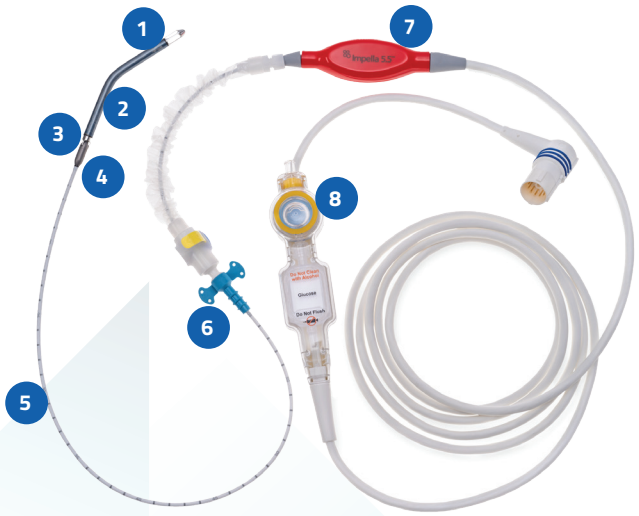
Sodium bicarbonate compatible luer – heparin-free purge alternatives

Connections – 1 luer connection for purge fluid and integrated purge tubing

Modular purge cassette for simplified line management

Overview

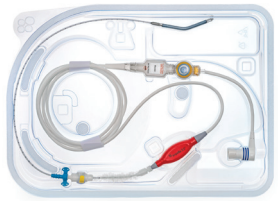
1. Inlet
2. Cannula
3. Outlet
4. Motor Housing
5. Catheter Shaft
6. Blue Suture Hub
7. Red Impella Plug
8. Purge Filter Unit



ABIOMED®
Recovering hearts. Saving lives.

Impella 5.5® with SmartAssist®

Accessories



Impella 5.5 Kit

Part number: 1000100

- Impella Catheter (2000193)
- Purge Cassette (2000171)
- 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: 1000185

5 Package: 1000200

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.

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 cm^2 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.abiomed.com/important-safety-information** to learn more.

Clinical Support
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