Impella CP® with SmartAssist®

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 5 days for indications including support during high-risk PCI and support post AMI (refer to Indications on the back of this document)
- Heart pump provides peak flow up to 4.3 L/min for systemic perfusion
- Outlet located in the ascending aorta supports coronary perfusion
- Enables repositioning in the ICU without imaging*

Peak flow up to **4.3** L/min

1. Impella CP with SmartAssist Heart Pump
2. Catheter Shaft
3. StatLock® Suture Pad
4. Reaccess Sheath
5. Anticontamination Sleeve
6. Impella Plug with Sidearm

**Impella CP with SmartAssist Specifications**

- **Maximum Flow:** 4.3L/min
- **Maximum Mean:** 3.7 L/min
- **Speed Range:** 0 to 46,000 rpm
- **Diameter:** 9 Fr Catheter, 14 Fr pump, 6 Fr pigtail
- **Interventional Length:** 92-98cm

**Cannula:**
Polyurethane coated nitinol with a 145-degree angle

**Easy Guide 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

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* For Ventricularized pumps only
**Automated Impella® Controller**

Part number: 0042-0010 EU

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

**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.

**Introducer kit**

Part number: 0052-3025

Vascular access kit used for percutaneous insertion of the Impella catheter.

- 14 Fr x 13 cm and a 14 Fr x 25 cm Peel-away introducers with hemostatic valve
- 8, 10, 12, 14 Fr Dilators
- 0.035" x 150 cm Guidewire

**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.

**Impella CP Kit**

Part number: 0048-0014

- Impella Catheter (0048-0008)
- Introducer Kit (0052-3025)
- Purge Cassette (0043-0001)
- 0.018” x 260cm placement guidewire (0052-3005)

**LETS SIDE SUPPORT**

**Indications for Use**

Impella CP®: The Impella (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 5 days for the following indications, as well as others:

- The Impella is a circulatory support system for patients with reduced left ventricular function, e.g., post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction, or for myocardial protection after acute myocardial infarction.
- The Impella may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome.
- Support during high risk percutaneous coronary intervention (PCI)
- Post PCI

**CONTRAINDICATIONS**

- Mechanical aortic valves, severe aortic valvular stenosis or valvular regurgitation
- Hematological disorder causing fragility of the blood cells or hemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrosis or severe anomaly of the ascending aorta and / or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) after myocardial infarction
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PADO) is a relative contraindication

**POSSIBLE COMPLICATIONS**

There are risks of complications with every procedure using a blood pump. These include among others:

- Hemolysis
- Bleeding
- Immune reaction
- Embolism, thrombosis
- Vascular injury through to angionecrotomy
- Positioning problems
- Infection and septicemia
- Dislocation of the pump
- Cardiovascular injuries due to extreme movement of the suction cannula in relation to the cardiac valve or as a result of attachment by suction of the pump to the valve system following incorrect positioning
- Endocardiac injuries as a result of attachment of the pump due to suction
- Pump failure, loss of pump components following a defect
- Patient dependency on the pump after use for support

In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella devices. For more information please see the Instructions for Use Manual.

Learn more visit: www.abiomed.com/important-safety-information

**Clinical Support Center**

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