STEP-BY-STEP GUIDE

Left Heart Unloading

Impella CP® with SmartAssist®

Femoral Insertion

The Impella CP with SmartAssist heart pump is approved for use in high-risk percutaneous coronary intervention and cardiogenic shock and is proven to unload the left ventricle and support systemic circulation.[1] The Impella catheter is an intravascular blood pump that supports a patient's circulatory system. The Impella CP can be inserted percutaneously through the femoral or axillary artery and into the left ventricle.

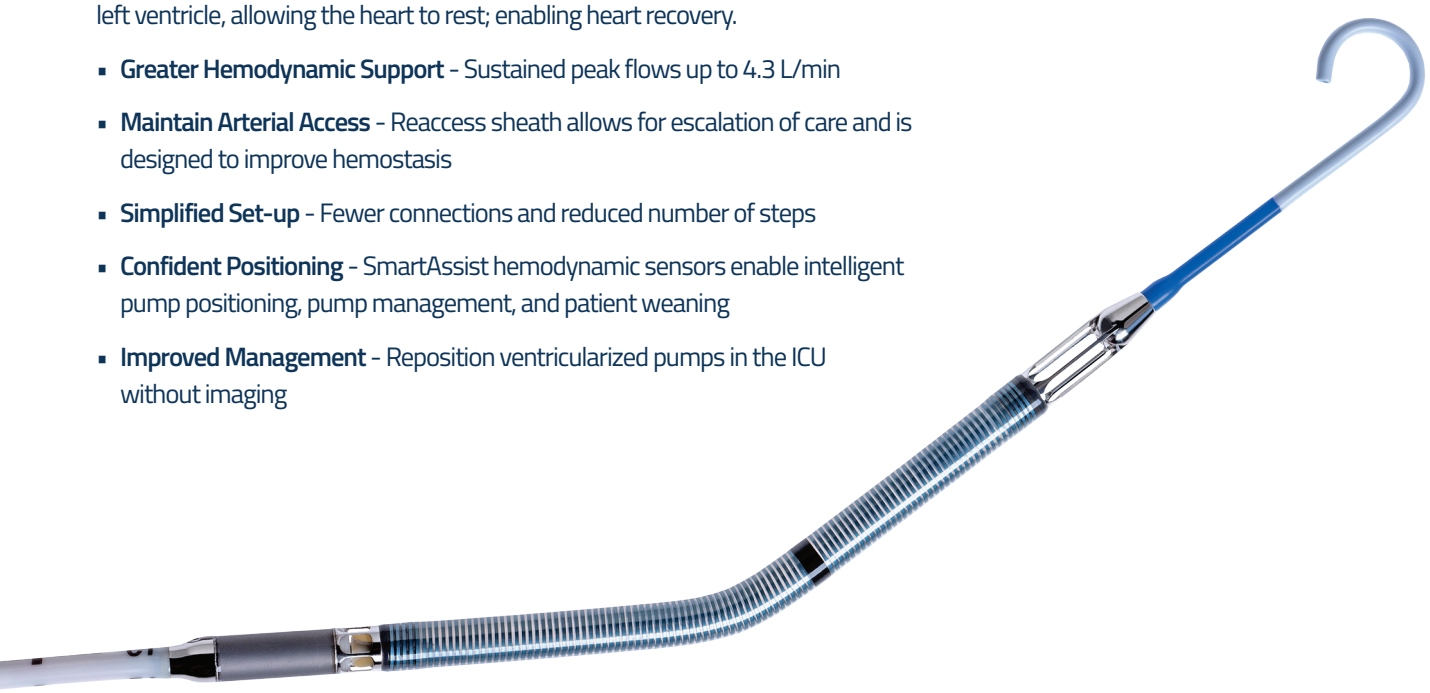
When properly positioned, the Impella catheter delivers blood from the inlet area, which sits inside the left ventricle, through the cannula, to the outlet opening in the ascending aorta.

Having the opportunity to rest the left ventricle has been proven to increase heart recovery while keeping other therapeutic options open. The Impella CP with SmartAssist heart pump may provide these benefits while minimizing complications to the patient.[2]

Device Summary

A minimally invasive heart pump delivering full forward flow, directly unloading the left ventricle, allowing the heart to rest; enabling heart recovery.

- **Greater Hemodynamic Support** - Sustained peak flows up to 4.3 L/min
- **Maintain Arterial Access** - Reaccess sheath allows for escalation of care and is designed to improve hemostasis
- **Simplified Set-up** - Fewer connections and reduced number of steps
- **Confident Positioning** - SmartAssist hemodynamic sensors enable intelligent pump positioning, pump management, and patient weaning
- **Improved Management** - Reposition ventricularized pumps in the ICU without imaging



Clinical support 24 hours per day, 7 days a week
1-800-422-8666 (US)

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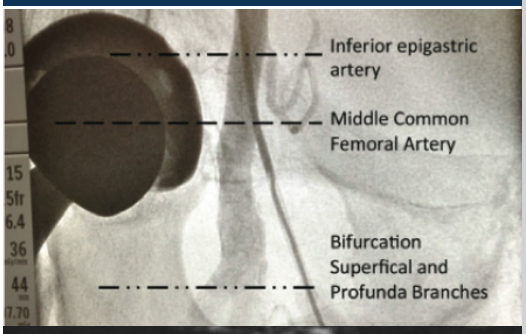
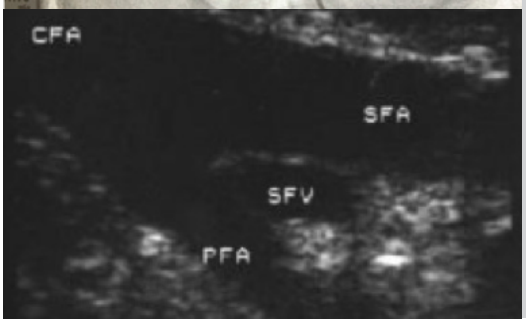
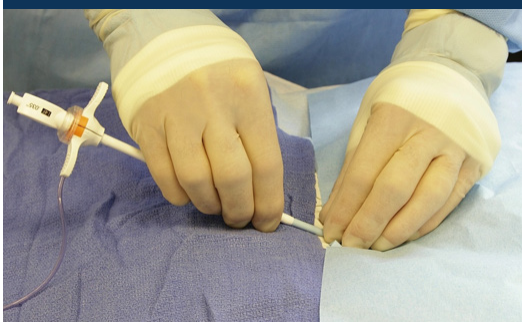
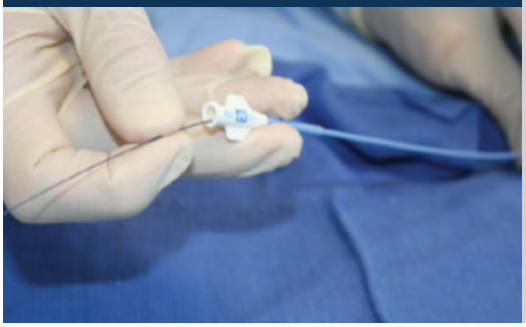
Left Heart Unloading with the Impella CP with SmartAssist

Surgical Step	Instrumentation	Recommendations
1. Access Common Femoral Artery  	▪ Fluoroscopy ▪ Ultrasound ▪ Micropuncture	Use ultrasound guidance and micropuncture kit for access to ensure proper insertion into the common femoral artery, above the bifurcation of the SFA and profunda and below the inferior epigastric artery. A low insertion angle, 35° should be used for minimal arterial lift once sheath in place. Assess distal angiogram of groin to visualize possible calcification, stenosis and/or tortuosity. Implantation of Impella CP requires a 4.67mm vessel. ***Image 2 source:*** *worldwidewounds.com/2000/sept/Michael-Lunt/Doppler-Imaging.html*
2. Pre-dilate, Insert 14 Fr Sheath Over Stiff 0.035" Guidewire 	▪ 8, 10, 12 Fr dilators ▪ Stiff 0.035" guidewire ▪ 14 Fr Peel-Away Introducer (13 or 25cm length) ▪ Syringe ▪ Heparinized saline	Support 14 Fr introducer shaft with dilator in place while advancing into the artery. Once sheath has been placed, administer heparin to achieve an ACT ≥ 250 seconds prior to removing the dilator to prevent thrombus formation in the introducer.
3. Advance 0.035" Guidewire with Diagnostic Catheter Across the Aortic Valve 	▪ Standard 0.035" guidewire ▪ Pigtail, AL1 or Multipurpose diagnostic catheter ▪ 0.018" guidewire ▪ Fluoroscopy	Advance a standard 0.035" guidewire with a diagnostic catheter and navigate to pass the aortic valve. Remove the 0.035" guidewire and replace with provided 0.018" guidewire. Once guidewire is in apex of ventricle, remove the catheter.

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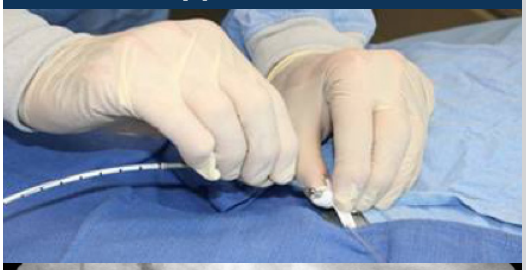
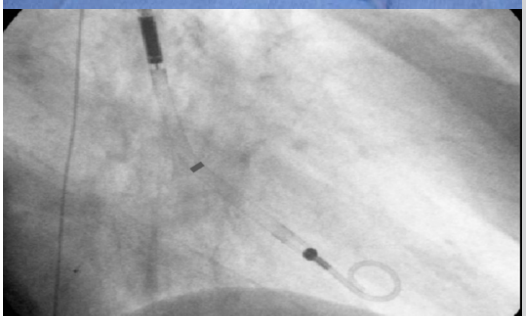
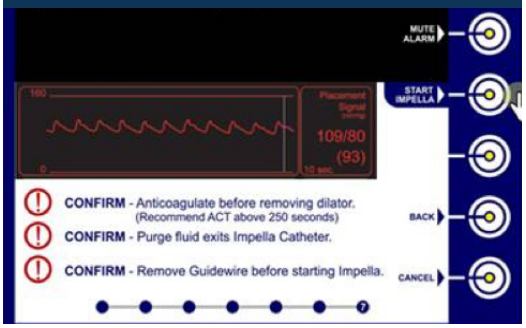
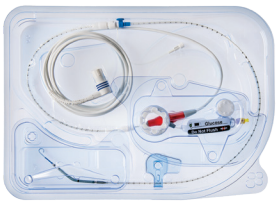
Surgical Step	Instrumentation	Recommendations
4. Backload the Impella Device Using EasyGuide Lumen 	▪ EasyGuide lumen inside the Impella CP pigtail and cannula ▪ 0.018" guidewire	Backload the Impella CP using the red EasyGuide lumen onto the 0.018" guidewire and advance until it exits the red lumen near the label. Remove the EasyGuide lumen by gently pulling the label in line with the Impella catheter shaft **NOTE:** If the EasyGuide lumen is removed from the Impella catheter before backloading onto the guidewire, **DO NOT REINSERT.** Backload the Impella catheter on the 0.018" guidewire aligning the placement wire to exit the outlet area and align with the straight black line on the catheter.
5. Place Impella Across the Aortic Valve & Confirm Position with Fluoroscopy  	▪ 0.018" guidewire ▪ Impella CP Catheter ▪ Fluoroscopy	Advance Impella device through the hemostatic valve of the sheath. Once the motor housing is through the valve, using fluoroscopic guidance, continue to advance the catheter over the wire until it crosses the aortic valve. Center the radiopaque marker on the Impella CP at the level of the aortic valve. Slowly remove the 0.018" guidewire from the Impella.
6. Start the Impella CP 	▪ AIC ▪ Fluoroscopy	Confirm the guidewire has been removed. Press the **START IMPELLA** soft button and press OK to start the Impella CP. Verify proper placement of the Impella device with fluoroscopy. Make sure the Impella does not migrate into the LV while ramping up support. Monitor the Placement Screen on the AIC to ensure aortic placement signal and pulsatile motor current. Reposition if needed and remove excess catheter slack in aortic arch.

Accessories



Impella CP with SmartAssist Kit

Part number: 0048-0003

- Impella Catheter (0048-3092)
- Purge Cassette (0043-0001)
- Introducer Kit (0052-3025)
- 0.018", 260cm placement guidewire (0052-3005)

0.018", 260cm Placement Guidewire

Part number: 0052-3005

Purge Cassette

5 Package: 0043-0003

Introducer Kit

Part number: 0052-3025

- 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

Place an order email: ***Orders@abiomed.com***

References

1. Abiomed data on file.

2. Aghili, N et. al. Biventricular Circulatory Support Using 2 Axial Flow Catheters for Cardiogenic Shock Without the Need for Surgical Vascular Access. Circ Cardiovasc Interv. 2016; 9:1-3

IMPELLA® INDICATION & SAFETY INFORMATION

IMPELLA® LEFT-SIDE DEVICES

High-Risk PCI

The Impella 2.5®, Impella CP® and 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, Impella CP, and 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®, 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 0.6cm^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 ***http://www.abiomed.com/impella*** to learn more.

IMP-653.v2

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