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.

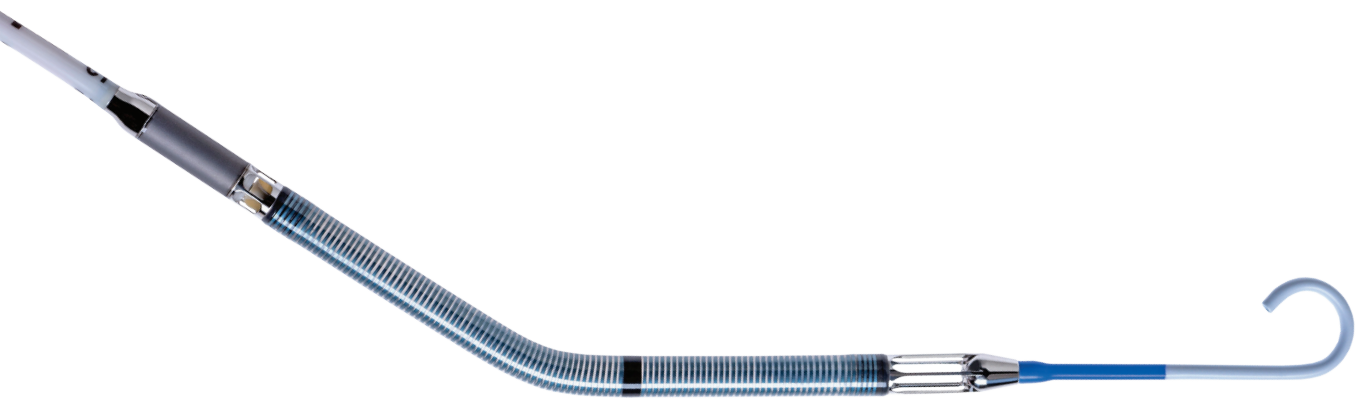
When properly positioned, the Impella catheter delivers blood from the inlet area, which sits inside the left ventricle, through the cannula, to the outlet opening in the ascending aorta.

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



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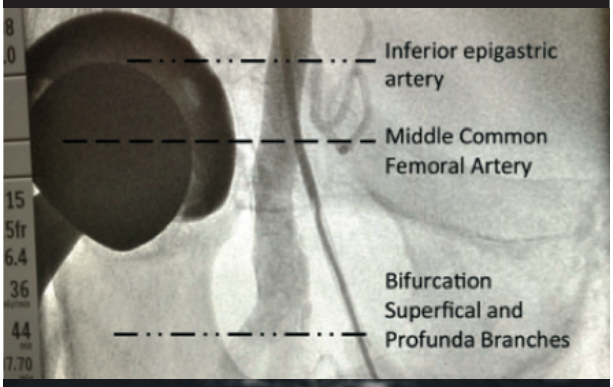
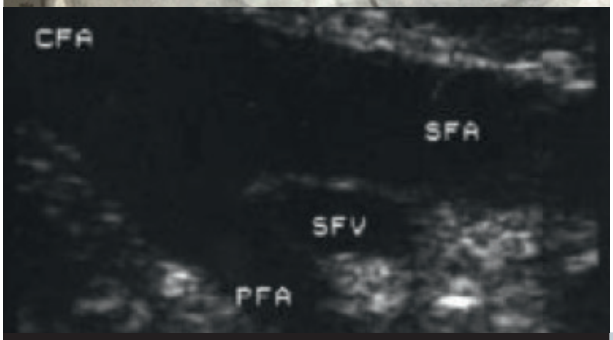
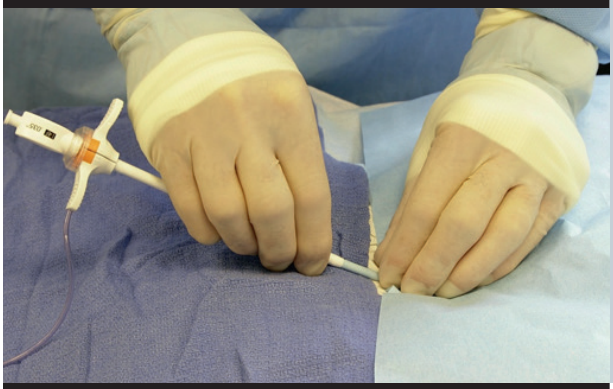
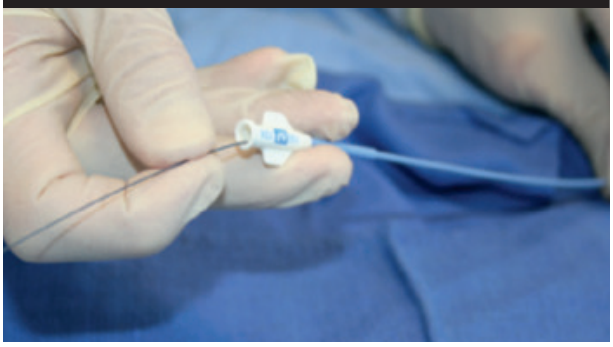
ABIOMED®

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 a 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. Insertation of Impella CP requires a 4.67mm vessel. ***Image 2 source:*** *worldwidewounds.com/2000/sept/Michael-Lunt/Doppler-Imaging.html*
2. Predilate, 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	Predilate the vessel with the included sequential dilators. 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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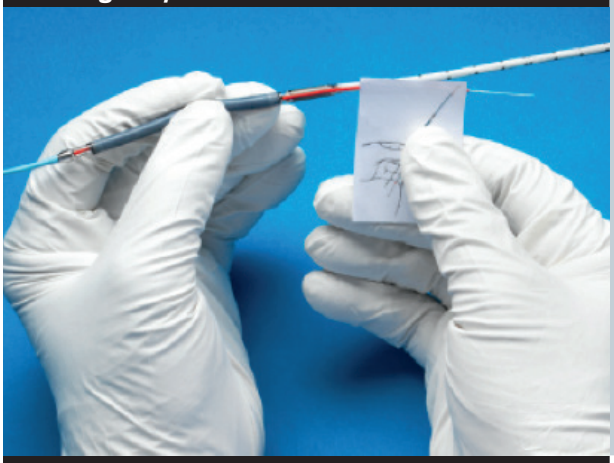
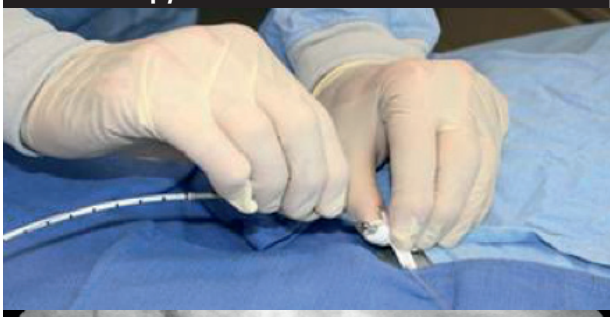
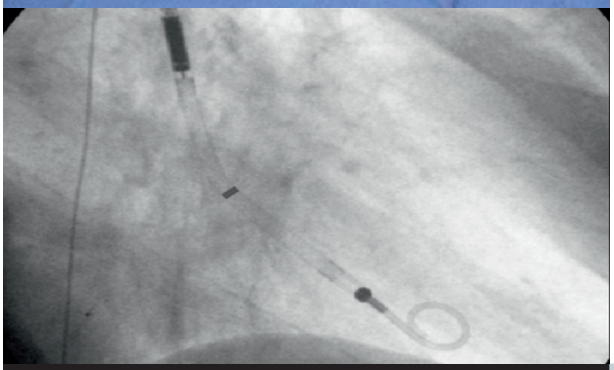
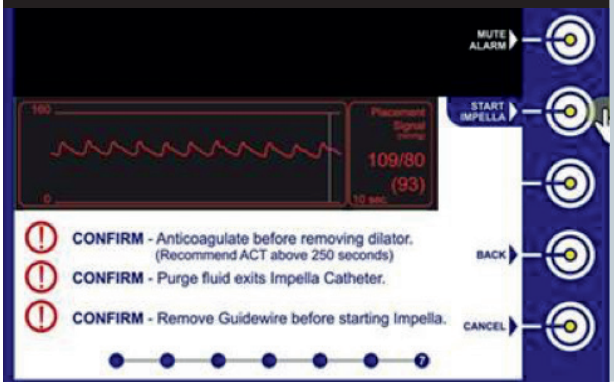
Surgical Step	Instrumentation	Recommendations
4. Backload the Impella Device Using EasyGuide Lumen 	▪ EasyGuide lumen inside the Impella CP pigtail and cannula ▪ 0.018" guidewire	Backload the Impella CP pump using the red EasyGuide lumen onto the 0.018" guidewire and advance until it exits the red lumen 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 the Impella device 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 pump.
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 pump 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.

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 (EU)

LEFT-SIDE Support

INDICATIONS FOR USE:
Device: Impella CP with SmartAssist®:
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 necrotomy or severe anomaly of the ascending aorta and / or the aortic arch
- Ventricular septal defect (VSD) after myocardial infarction
- Mural thrombus in the left ventricle
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PAOD) 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
- Cardiovalvular 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 Manuals.

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