STEP-BY-STEP GUIDE

# Left Heart Unloading

## with The Impella 5.0® Heart Pump

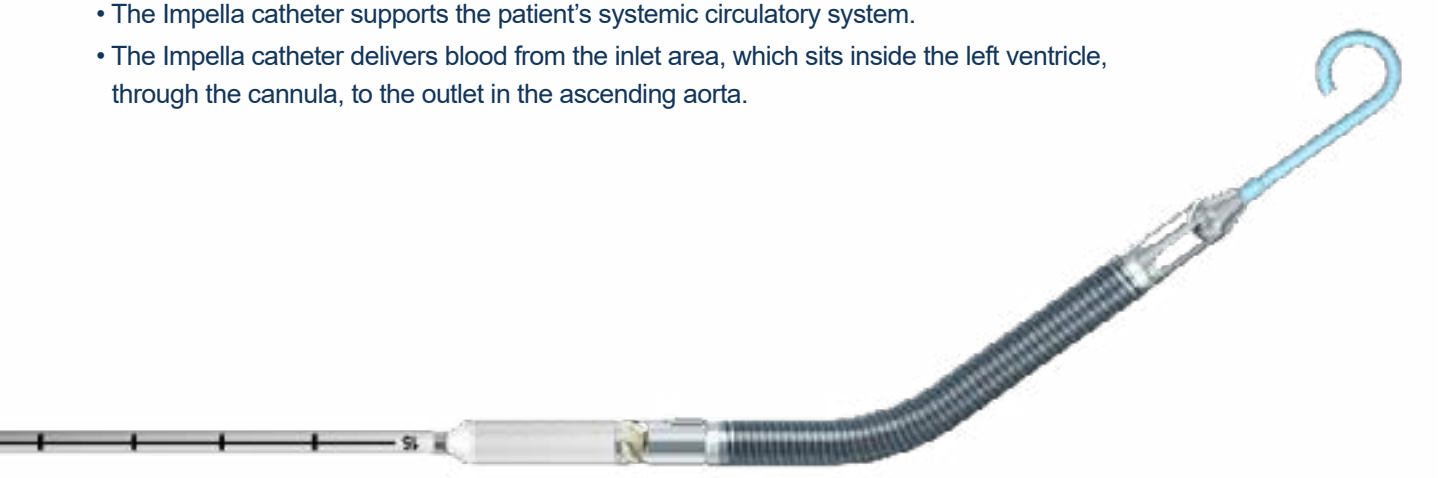
The Impella 5.0 is approved for use in cardiogenic shock, and is proven to unload the left ventricle and support the systemic circulation.[1]

Having the opportunity to immediately ambulate patients, resting the left ventricle, has proven to increase heart recovery while keeping other therapeutic options open. The Impella 5.0 heart pump may provide these benefits while minimizing complications to the patient.[2]

**Device Summary**

The Impella 5.0 heart pump is an intravascular microaxial blood pump that delivers up to 5.0 L/min of forward flow from the left ventricle to the aorta.

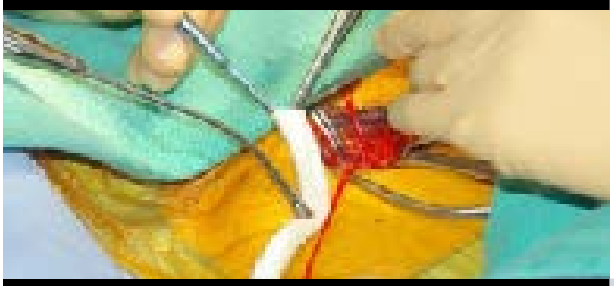
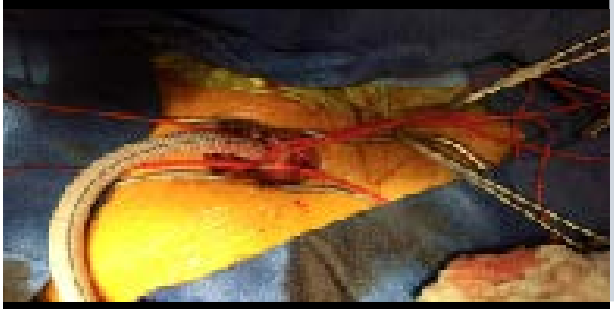
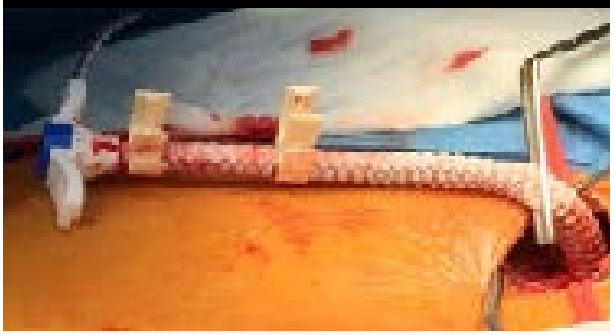
- The Impella catheter supports the patient's systemic circulatory system.
- The Impella catheter delivers blood from the inlet area, which sits inside the left ventricle, through the cannula, to the outlet in the ascending aorta.



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

ABIOMED

# Left Heart Unloading with the Impella 5.0

| Surgical Step | Instrumentation | Recommendations |
|---|---|---|
| 1. Expose the axillary artery  | • Proximal & distal vessel loops to expose and control bleeding | Once exposed you will need to evaluate the size of the axillary artery. For the implantation of the Impella 5.0 a 7mm vessel is required. If the vessel is < 7mm an Impella CP may be considered for use. |
| 2. Arteriotomy  | • Sidebiter clamp<br>• 11 blade | Create an arteriotomy large enough for the graft that you are using. For the Impella 5.0 catheter a 10mm graft is required.<br><br>For the insertion of the Impella 2.5® or Impella CP®, an 8mm graft may be used. |
| 3. Preparing the graft  | • 10mm Hemashield Platinum Woven Dacron Graft<br>-or-<br>• 10mm Terumo Vascutek Gelweave (woven ) | A 60-70 degree bevel should be made on the graft. This allows the device to transition into the vessel at a straight angle, allowing for a smooth delivery of the Impella device. |
| 4. End to side anastomosis  | • Vascular clamp above anastomosis and release your proximal vessel loop to assess the integrity of the suture line | Ensure proximal and distal vessel loops are used to maintain hemostasis. Use a standard "end to side" anastomosis to suture the graft to the artery. |
| 5. Insert 23Fr axillary sheath  | • 23Fr axillary sheath<br>• 2 graft locks | Clamp the graft and insert the 23Fr axillary sheath.<br><br>After assessing the integrity of the anastomosis, insert the 23Fr axillary sheath into the graft. Using the included Graft Locks, secure the graft to the sheath. One or two may be used. |

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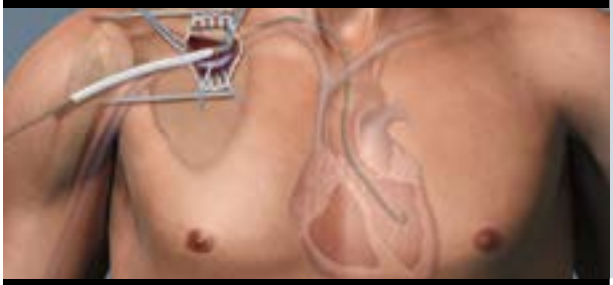
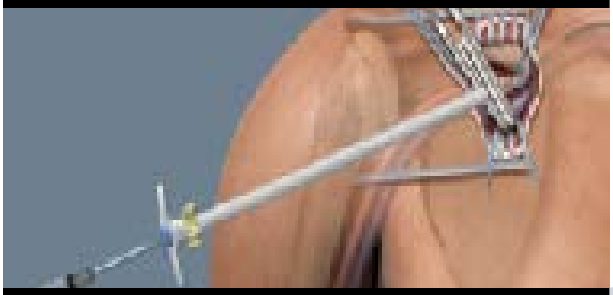
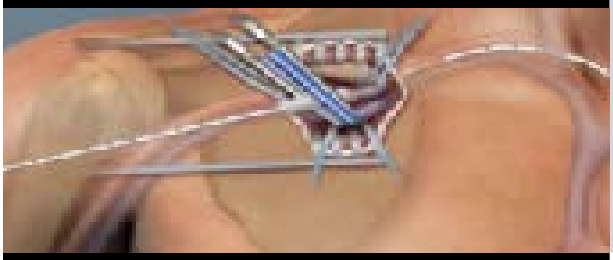
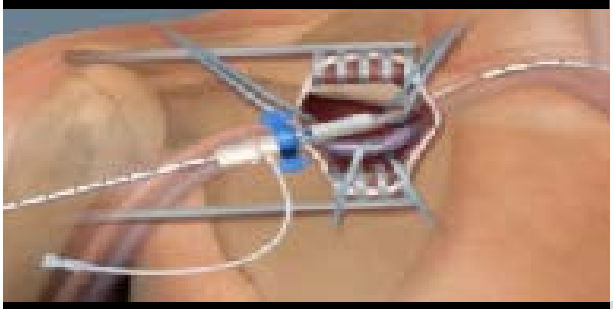
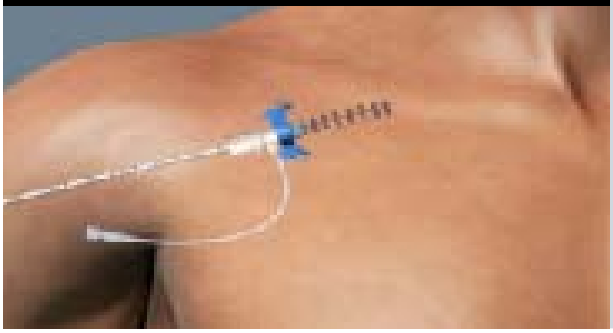
|---|---|---|
| 6. Advance .035 wire with the catheter across the aortic valve  | • .035 wire<br>• Pigtail, AL1, or Multipurpose diagnostic catheter<br>• Soft jawed vascular clamp<br>• Fluoroscopy/ C-Arm | Advance an 0.035" wire with a diagnostic catheter through the ascending aorta and navigate to pass the aortic valve. Remove the 0.035" wire and replace with provided 0.018" wire. Once wire is in apex of ventricle, remove the catheter and clamp the graft above the anastomosis.<br><br>Note: the use of a vascular clamp on the graft above the anastomosis during insertion through the valve to eliminate bleeding. |
| 7. Place the Impella 5.0  | • .018 wire<br>• Impella 5.0 | Backload the Impella 5.0 and introduce the pump through the hemostatic valve of the sheath. Once the motor housing is through the valve, release the clamp and continue to advance the catheter until it crosses the aortic valve. Confirm placement with fluoroscopic guidance. |
| 8. Trim the graft  | • Soft jawed vascular clamp<br>• Tighten the proximal & distal vessel loops to control bleeding | Once the device is placed and running, place a soft jawed vascular clamp at the graft anastomosis.<br><br>Remove the graft lock(s). Remove the introducer sheath from the graft and peel away. Trim the graft longitudinally down to the level of the skin and remove so that there will be no exposed graft. |
| 9. Advance repositioning sheath  | | The repositioning sheath should be advanced completely into the graft. The graft should be tied to the sheath along one of the three suture ribs.<br><br>Utilize proximal vessel loop to control hemostasis while advancing the sheath into the shortened graft since the soft jawed clamp will have to be removed to advance the sheath. |
| 10. Incision closure  | | Suture down the repositioning sheath, reconfirm that all slack has been removed. Advance the sterile sleeve and attach to the repositioning sheath.<br><br>Tighten the tuohy borst by turning clockwise until finger-tight. |

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

INDICATIONS FOR USE

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

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