

STEP-BY-STEP GUIDE

Left Heart Unloading Impella CP[®] with SmartAssist[®] heart pump

Axillary 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 with SmartAssist 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 recover.

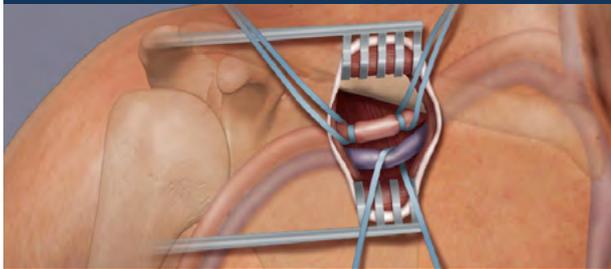
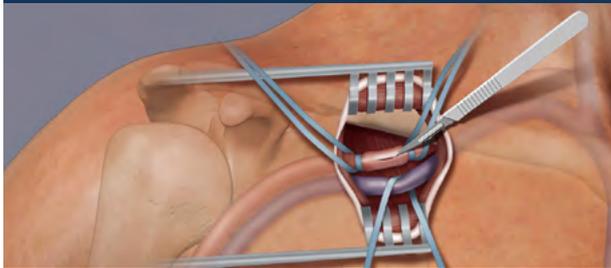
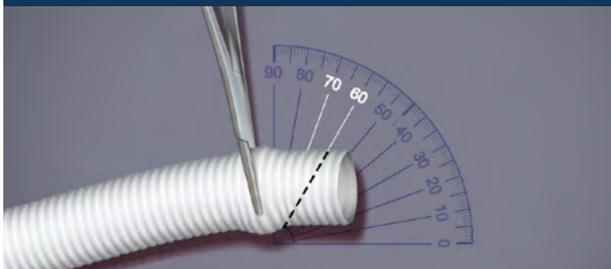
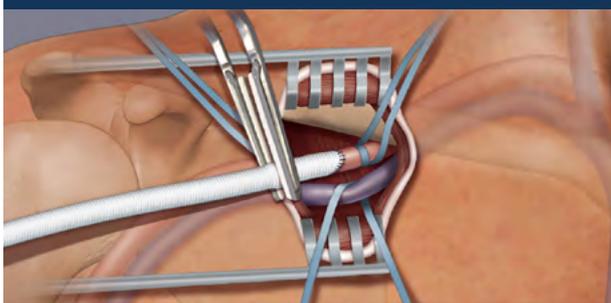
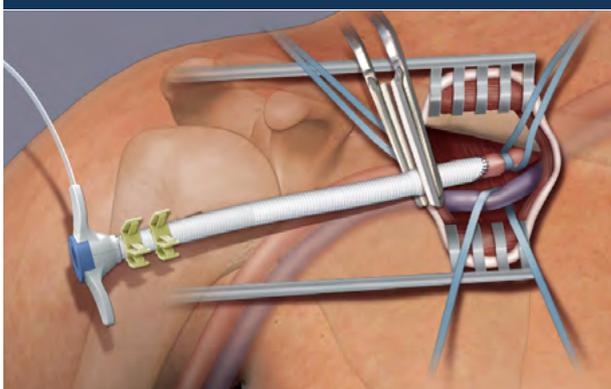
- **Greater Hemodynamic Support** - Sustained peak flows up to 4.3 L/min
- **Maintain Arterial Access** - Reaccess sheath allows for escalation of care and is designed to improve hemostasis
- **Simplified Set-up** - Fewer connections and reduced number of steps
- **Confident Positioning** - SmartAssist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

Insertion kit (axillary) 0052-0011 EU
must be ordered separately!

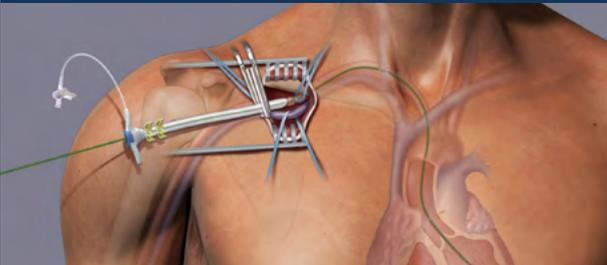
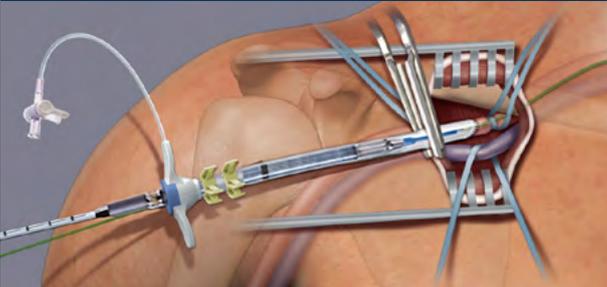
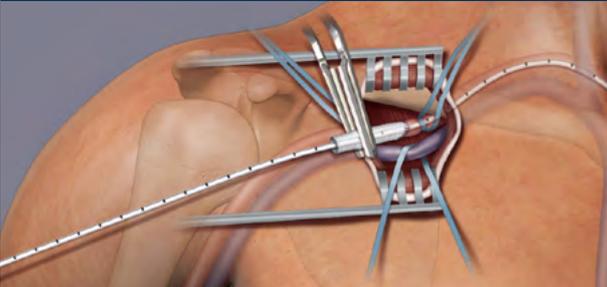
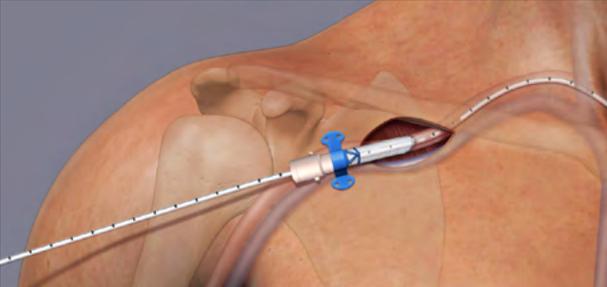
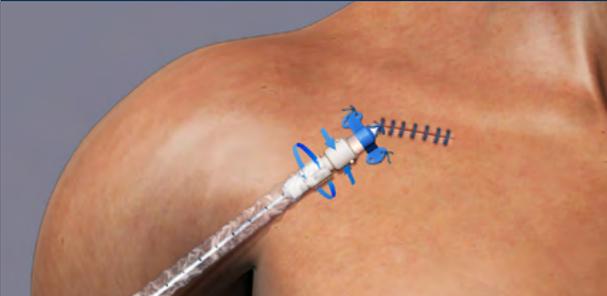
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 **ABIOMED[®]**

Left Heart Unloading with the Impella CP with SmartAssist heart pump

Surgical Step	Instrumentation	Recommendations
<p>1. Expose the axillary artery</p> 	<ul style="list-style-type: none"> Proximal & distal vessel loops to expose and bleeding 	<p>Once exposed you will need to evaluate the size of the axillary artery. For the insertion of the Impella 5.5 heart pump a 6 mm vessel is required. If the vessel is < 6 mm an Impella CP heart pump may be considered for use.</p> <p>Note: Tunneling is discouraged due to the pump's low profile.</p>
<p>2. Arteriotomy</p> 	<ul style="list-style-type: none"> Sidebiter clamp 11 blade 	<p>Create an arteriotomy large enough for the graft that you are using.</p> <p>For the insertion of the Impella CP with SmartAssist pump, the 23 F axillary sheath can be used with a 10 mm x 20 cm graft.</p> <p>Alternatively, the 14 F insertion sheath (from Impella CP introducer Kit) and a 8 mm x 20cm graft can be used.</p>
<p>3. Preparing the graft</p> 	<ul style="list-style-type: none"> 8 or 10 mm Hemashield Platinum Graft -or- 8 or 10 mm Terumo Vascutek Gelweave (woven) 	<p>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.</p>
<p>4. End to side anastomosis</p> 	<ul style="list-style-type: none"> Vascular clamp above anastomosis and release your proximal vessel loop to assess the integrity of the suture line. 	<p>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.</p>
<p>5. Insert 23 Fr axillary sheath*</p> 	<ul style="list-style-type: none"> 23 Fr axillary sheath* 2 graft locks 	<p>If the Axillary Insertion Kit is used: Clamp the graft and insert the 23 Fr axillary sheath.</p> <p>After assessing the integrity of the anastomosis, insert the 23 Fr sheath into the graft. Using the included Graft Locks, secure the graft to the sheath. One or two may be used. If a graft other than the Hemashield Platinum is used, 2 graft locks are recommended to maintain hemostasis. In this situation, both graft locks should be placed between the retainers and the hub on the introducer to prevent the introducer from sliding out of the graft.</p> <p>If an 8 mm graft and the 14 F insertion sheath is used: Perform a cutdown of the axillary artery and attach a 8 mm vascular graft, clamp at the anastomosis. Place the 14 Fr peel-away sheath into the vascular graft and secure with umbilical tape or heavy silk ties.</p>

*Insertion kit (axillary) 0052-0011 EU must be ordered separately and is not included in the Impella CP with SmartAssist pump kit.

Surgical Step	Instrumentation	Recommendations
<p>6. Advance 0.035 wire with the catheter across the aortic valve</p> 	<ul style="list-style-type: none"> 0.035" diagnostic guidewire Pigtail, AL1, or Multipurpose diagnostic catheter Softjawed vascular clamp Fluoroscopy/C-Arm 	<p>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 diagnostic catheter and clamp the graft above the anastomosis.</p> <p>Note. Use vascular clamp on the graft above the anastomosis during insertion through the valve to eliminate bleeding.</p>
<p>7. Place the Impella CP® with SmartAssist</p> 	<ul style="list-style-type: none"> 0.018" placement guidewire Impella CP with SmartAssist 	<p>Backload the Impella device and 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 fluoroscopy and TEE. Position inflow bend or elbow at the valve (inflow should be 3,5 cm below AV).</p>
<p>8. Trim the graft</p> 	<ul style="list-style-type: none"> Soft jawed vascular clamp Tighten the proximal & distal vessel loops to control bleeding 	<p>Once the device is placed and running, place a soft jawed vascular clamp at the graft anastomosis.</p> <p>Remove the graft lock(s) or the umbilical tape. 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.</p>
<p>9. Advance the blue suture hub</p> 		<p>The blue suture hub should be completely into the graft. The graft should be tied to the sheath along one of the three suture ribs.</p> <p>Utilize proximal vessel loop to control hemostasis while advancing the blue suture hub into the shortened graft since the soft jawed clamp will have to be removed to advance the blue hub.</p>
<p>10. Incision closure</p> 		<p>Suture down the blue suture hub. Advance the sterile sleeve and attach to the blue suture hub, confirm that all slack has been removed.</p> <p>Tighten the Tuohy Borst by turning clockwise until finger tight. If needed, maintain blue suture hub angle with folded 4x4's before placing sterile dressing.</p>

11. External Fixations



Secure Impella catheter near Tuohy-Borst/blue hub with commercial catheter locks (Foley, Statiock).

Secure connector cable adjacent to red Impella handle.

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:

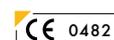
- Mechanical aortic valves, severe aortic valvular stenosis or valvular regurgitation
- Hematological disorder causing fragility of the blood cells or hemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrotomy or severe anomaly of the ascending aorta and / or the aortic arch
- 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 angioneurotomy
- 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
- Endocardial 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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