Impella® Procedure with SINGLE-ACCESS TECHNIQUE

Procedural Steps

Abiomed's Impella CP® & Impella CP with SmartAssist® heart pumps introducer has recently been CE marked, and is being released to users. It has a 14 French (Fr) sheath, which permits placement of the Impella CP and Impella CP with SmartAssist heart pump. However, after the Impella CP and Impella CP with SmartAssist heart pump is positioned in the ventricle, its smaller Impella 9 Fr catheter shaft remains in the introducer. The size difference between the 14 Fr sheath and 9 Fr catheter shaft permits the insertion of a second introducer sheath (up to 7 Fr) adjacent to the 9 Fr catheter shaft, using a new technique. The additional sheath can be used to pass other catheters, including interventional devices. Use of the new technique, called the "single-access approach", results in one access site for both the Impella CP device and an additional catheter.

PCI Access Site Options

Only for use with the Impella CP and Impella CP with SmartAssist
14 Fr introducer sheath

Clinical Support Center 24 hours per day, 7 days a week:
+49 (0) 1805 2246633 (EU)
**Impella CP and Impella CP with SmartAssist Heart Pump**

**SINGLE-ACCESS TECHNIQUE**

**Procedural Steps**

After you have placed the Impella catheter using access best practices...

<table>
<thead>
<tr>
<th>PROCEDURE STEPS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1.</strong> Aspirate and flush Impella sheath</td>
</tr>
<tr>
<td><strong>Step 2.</strong> Place needle through diaphragm of Impella sheath at the 10:00 or 2:00 position to allow for placement of 0.035&quot; guidewire</td>
</tr>
<tr>
<td><strong>Step 3.</strong> Secure the Impella catheter to avoid any movement and insert PCI sheath over 0.035&quot; guidewire</td>
</tr>
<tr>
<td><strong>Step 4.</strong> Perform Protected PCI</td>
</tr>
<tr>
<td><strong>Step 5.</strong> Remove PCI sheath at end of procedure, while securing the Impella catheter</td>
</tr>
</tbody>
</table>

Remove Impella and close access site per recommendations
Abiomed recommends fixating the Impella catheter shaft while advancing secondary sheath.

**Potential Complications:** There are no additional complications related to use of the single-access approach. See the Impella CP and Impella CP with SmartAssist 14 Fr introducer sheath Instructions for Use found by visiting: www.heartrecovery.de/produkte-und-services/impella for a complete list of the complications related to its use.

Following current best practice, it is critical to fix the Impella shaft under fluoroscopy while advancing the sheath. Movement of the Impella catheter while advancing the secondary sheath is most common while using non-hydrophilic 7 Fr sheaths.

Following current best practice, care should be taken when inserting the secondary sheath to prevent sheath damage. Additionally, dilators and catheters should be removed slowly as rapid removal may damage the valve membrane resulting in blood flow through the valve.

When using the Impella 14 Fr sheath for single-access, a secondary access point is no longer available to manage complications.

**Troubleshooting noted above is the same as current Impella procedures**
INDICATIONS FOR USE

Device: Impella CP®, 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 necrothomy or severe anomaly of the ascending aorta and/or the aortic arch
• Mural thrombus in the left ventricle
• Hemolysis
• 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 (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 sepsisemia
• 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
• 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. Visit www.abiomed.de to learn more.