Impella® Procedure with **SINGLE-ACCESS TECHNIQUE**

Procedural Steps

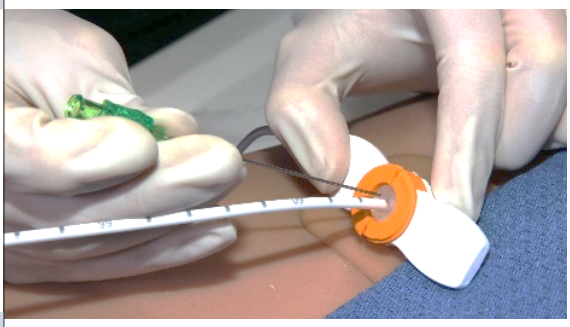
Abiomed's Impella CP Introducer* was recently FDA cleared[1], and is being released to users. It has a 14 French (F) sheath, which permits placement of the Impella CP's pump (motor and housing). However, after the Impella CP pump is positioned in the ventricle, its smaller Impella 9 F catheter shaft remains in the introducer. The size difference between the 14 F sheath and 9 F catheter shaft permits the insertion of a second introducer sheath (up to 7 F) adjacent to the 9 F 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.

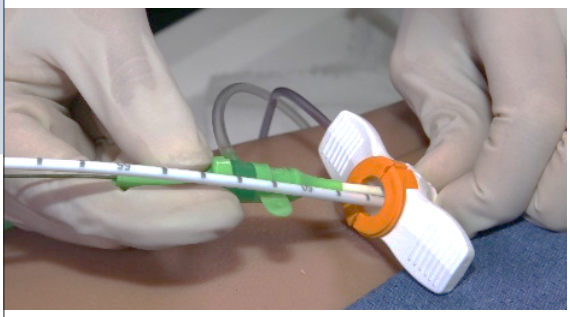
Only for use with the Impella CP 14 F introducer sheath

Impella CP® Heart Pump
SINGLE-ACCESS TECHNIQUE
Procedural Steps

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

PROCEDURE STEPS	
Step 1.	Aspirate and flush Impella sheath
Step 2.	Place needle through diaphragm of Impella 14F sheath at the 10:00 or 2:00 position to allow for placement of 0.035” guidewire
Step 3.	Secure the Impella catheter to avoid any movement and insert PCI sheath over 0.035” guidewire
Step 4.	Perform Protected PCI
Step 5.	Remove PCI sheath at end of procedure, while securing the Impella catheter





Remove Impella and close access site per recommendations

Single-Access
TROUBLESHOOTING
with the Impella CP 14 F introducer sheath

Bleeding from diaphragm
- Remove and re-access

Bleeding around sheath
- Tighten Perclose ProGlide® suture

Break in peel-away introducer along score lines
- Remove secondary sheath and peel away the Impella introducer, insert repositioning sheath; gain alternate access for PCI

Movement of Impella while advancing sheath
- Ensure catheter is fixed while advancing sheath

Abiomed recommends fixating the Impella catheter shaft while advancing sheath

Potential Complications: There are no additional complications related to use of the single-access approach. See the Impella CP Introducer's Instructions for Use found by visiting: ***http://www.abiomed.com/impella-device-instructions-for-use*** 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 F 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 F 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

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 0.6 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. Visit **www.abiomed.com/important-safety-information** to learn more.

1. *See www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K192769*

**Catalog numbers: 0052-3056, 0052-3057, 0052-3058*

For further information on single-access with the Impella 14 F sheath, please refer to the Instructions for Use or contact your local team and Abiomed's Clinical Support Center, 1-800-422-8666.

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