

PRODUCT UPDATE

January 2020



Impella
The World's Smallest Heart Pump

Use of the Impella CP[®] Introducer with the Single-Access Approach for Interventional Procedures

What's New

Abiomed's Impella CP Introducer* was recently FDA cleared¹, 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.

Recommendations

Background: Members of the clinical interventional cardiology community have developed the single-access approach described above. Clinical use of this technique has been presented at multiple interventional conferences, including TCT in 2018, and published as case studies from multiple centers.^{2,3} Use of the 14 F introducer for both Impella placement and the coronary guiding PCI catheter may reduce the number of required arterial access sites, and complications related to multiple access sites.⁴

Procedure in brief: For the new single-access approach using the Impella CP Introducer, first the Impella CP pump is inserted and positioned in the ventricle in the normal fashion. Then the Impella CP Introducer's hemostatic valve is punctured with an arteriotomy needle (either a micropuncture or a 18 G percutaneous entry needle) at the valve's upper left or right quadrants (10 or 2 o'clock position, see picture right). During needle insertion, care should be taken to avoid slits in the valve's diaphragm (central lumen), or bleeding may occur. This approach allows placement of an 0.035" stiff wire (available in the Impella kit) using Seldinger's technique through the valve adjacent to the 9 F catheter shaft. Next, the additional sheath can be placed over the wire. Dilation of the puncture is not required to place sheaths up to 7 F. The Impella CP Introducer's instructions for use, including details on use of the single-access approach can be found [here](#).



Best Practices: Abiomed has completed testing, which has shown its Impella CP Introducer is compatible with the single-access approach. Specifically, tests were completed to qualify the 7 F x 45 cm Terumo Pinnacle[®] Destination[®] Guiding sheath with 35 cm of hydrophilic coating. During the tests, it was noted that some resistance may be experienced when passing 7 F sheaths through the puncture, and manipulation of some interventional catheters (within the 7 F sheath) may be restricted. Hydrophilic coated sheaths significantly reduce the resistance experienced, and, therefore, are recommended when using a 7 F sheath. Both coated and uncoated 6 F sheaths are compatible with the single-access approach. Use of longer additional sheaths will result in less potential for interaction with the 9 F catheter shaft (when later manipulating interventional catheters). Once the additional sheath is inserted, the 9 F catheter shaft is fixed. In addition, when initially inserting the additional sheath, it is important to fix the 9 F catheter shaft to avoid antegrade migration of the Impella pump within the left ventricle. At the conclusion of the procedure, the additional sheath can be removed, and the Impella CP pump and the Impella CP Introducer can be removed using standard techniques.

The single-access approach is the only recommended approach for inserting an additional sheath through the Impella CP Introducer. If a user attempts to insert an additional sheath through the central portion of the valve, challenges with back bleeding may result.

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Patient selection: The single-access approach should be avoided in tall patients, tortuous iliac and aortic anatomy, procedures requiring second arterial access, and CTO procedures requiring an 8 F guide sheath.

Recommendations: The Impella CP Introducer is compatible with the single-access approach to place additional sheaths up to 7 F. The following 7 F sheaths should be avoided: Flexor® Raabe Guiding sheath, Cook® braided sheath, Cordis BRITE TIP® sheath, and Terumo GLIDESHEATH SLENDER® sheath and Pinnacle Destination sheath without hydrophilic coating. Once the sheath is placed, the Impella catheter may be difficult to reposition; therefore, it is critical to first place Impella pump into the ventricle, and then fix the position of the 9 F catheter shaft while inserting the additional sheath. For tall stature patients, it may be difficult to reach the coronary ostia using the single-access approach. The single-access approach is not compatible with the 13 F introducer provided with the Impella 2.5® catheter.

Potential Complications: There are no additional complications related to use of the single-access approach. See the Impella CP [Introducer's 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.

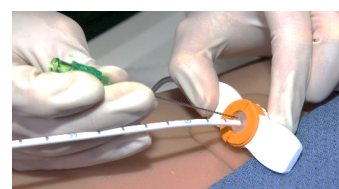
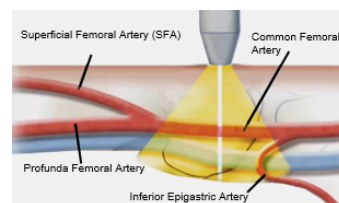
Following current best practice, care should be taken when inserting the secondary sheath to prevent sheath damage. Additionally, dilators and catheters should be removed slowly as rapid removal may damage the valve membrane resulting in blood flow through the valve.

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

Single-Access—Procedural Steps

After placing the Impella catheter using access best practices...

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|--------|---|
| Step 1 | Aspirate and flush Impella sheath |
| Step 2 | Place needle through diaphragm of Impella 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

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.

1. See www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K192769
2. Kumar, K, Reddy, S, Acharya, D, Lotun, K. (2019). Novel technique of performing multivessel PCI through an Impella sheath. *Catheter Cardiovasc Interv*, 1-4. doi: 10.1002/ccd.28583.
3. Wollmuth, J, Korngold, E, Croce, K, Pinto, D.S. (2019). The Single-access for Hi-risk PCI (SHiP) technique. *Catheter Cardiovasc Interv*, 1-3. doi: 10.1002/ccd.28556.
4. Kopin, D, Seth, M, Sukul, D, Dixon, S, Aronow, H.D, Lee, D, Tucciarone, M, Pielsticker, E, Gurm, H.S.(2019). Primary and Secondary Vascular Access Site Complications Associated With Percutaneous Coronary Intervention: Insights From the BMC2 Registry. *JACC Cardiovasc Interv*, 12(22):2247-2256. doi: 10.1016/j.jcin.2019.05.051.

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

Clinical Support
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IMP-1097

To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit:
www.abiomed.com/important-safety-information

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