

Quick Reference Guide

Direct Aortic Insertion

The next generation Impella 5.5™ with SmartAssist™ heart pump

The **Impella 5.5 with SmartAssist heart pump** is designed for providing full forward flow and intelligent patient management. The Impella 5.5 heart pump directly unloads the left ventricle reducing ventricular work for up to 29 days for indications including support during cardiogenic shock and delivers full cardiac support with maximum unloading, allowing the heart to rest and recover.

The Impella 5.5 heart pump is a microaxial, surgically inserted heart pump that unloads the left ventricle, reduces ventricular work, and provides the circulatory support necessary to allow recovery and early assessment of residual myocardial function. It is designed for long-duration support and enables ambulation to optimize recovery while using real-time SmartAssist intelligence.

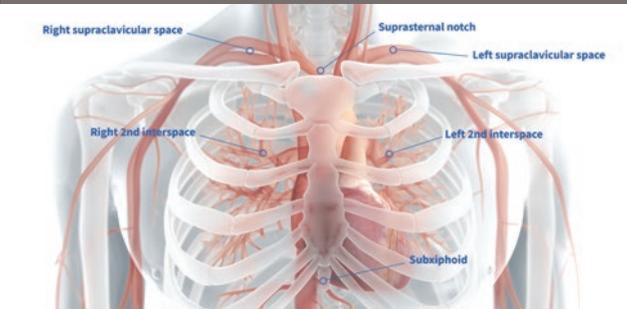


- **Full Hemodynamic Support** – Delivers flows up to 5.5 L/min
- **Ease of Insertion** – Optimized pump design & rigid cannula enhance deliverability & torque response
- **Ease of Use** – New intuitive catheter lock & pre-attached sterile sleeve enhance ease of use
- **Confident Positioning** – SmartAssist sensors to intelligently position heart pump, manage & wean patients
- **Designed for Ambulation** – Relocated purge sidearm improves external fixation & simplifies patient ambulation

Direct Aortic Insertion

This quick reference guide does not replace the instruction for use or product training.



PROCEDURE STEP	RECOMMENDATION
<p>1. Identify incision location</p> 	<p>Using the sterile incision template, identify the location for the incision on the ascending aorta, 7 cm above the plane of the aortic valve.</p>
<p>2. Create arteriotomy</p> 	<p>Place a sidebiter clamp on the aorta and size the aortotomy on the ascending aorta to accommodate a 10 mm woven Dacron graft proven suitable for this application and to ensure a smooth delivery of the Impella device.</p>
<p>3. Prepare and attach the graft</p> 	<p>Prepare a 10 mm woven vascular graft (e.g. Hemashield Platinum) by creating a bevel in accordance with your exit strategy.</p> <p>Attach the graft using the standard end-to-side anastomosis.</p>
<p>4. Prepare to exteriorize the catheter</p> 	<p>Clamp the graft above the anastomosis and confirm hemostasis.</p> <p>Create a 1.5-2.0 cm incision located 2 cm superior and two centimeters lateral to the sternal notch, parallel to the clavicle.</p> <p>Multiple options exist for exteriorizing the catheter.</p>
<p>5. Tunnel the graft</p> 	<p>Secure a traction suture to the end of the graft. Tunnel the graft from the ascending aorta, up and through the counter incision.</p> <p>Note: The graft from the ascending aorta traverses superiorly, passing posterior to the lateral border of the manubrium and sternoclavicular joint exiting the skin between the two heads of the sternocleidomastoid muscle.</p>

Impella 5.5™ Heart Pump

PROCEDURE STEP

RECOMMENDATION

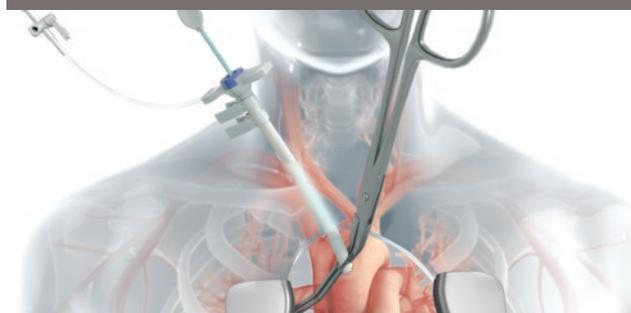
6. Insert the peel-away sheath



Insert the 23Fr peel away sheath. Use the included graft locks to secure the graft to the sheath.

An alternative option to the peel away sheath is preloading one 9mm silicone plug onto the catheter, secure with a ligature tie, and proceed with Impella insertion.

7. Lubricate valve and place Impella 5.5 catheter



Insert the provided 8Fr silicone dilator, passing it two to three times to lubricate the hemostatic valve, and then load the Impella 5.5 pump through the graft.

Release the clamp and then advance the Impella 5.5 catheter into the aorta. De-air the graft via the side-arm on the 23Fr Peel-away.

8. Confirm positioning



Hinweis: Da TEE-Ansichten (transösophageale Echokardiographie) 2D-Bilder liefern, wird empfohlen, die Katheterlage in mehreren Ebenen darzustellen.

Under TEE guidance, advance the inlet past the aortic valve.

Confirm placement of the catheter. The mid-inlet should measure approximately 5 cm below the aortic valve annulus.

9. Trim the graft



Once the Impella 5.5 is in place, place a soft jaw clamp above the graft anastomosis and gently pull any excess graft back through the incision site.

Remove the graft clamps and peel away sheath. Trim the graft and remove any excess.

10. Secure graft to suture hub



Advance the blue suture hub completely into the graft and secure it to the suture ribs with a heavy silk tie.

Suture down the blue suture hub.

SURGICAL STEP

RECOMMENDATION

11. Confirm security of Impella catheter



Confirm that all slack has been removed. The catheter should be able to move freely.

Remove the yellow locking pin and confirm the Impella catheter is secured in position.

12. Adjust catheter position, if necessary



If the Impella Catheter positioning needs to be adjusted, press and hold the blue button, while maintaining the angle of entry, and the catheter should move freely.

13. Finish procedure and secure Impella with catheter locks



Finish the procedure by closing the chest and placing a sterile dressing over the incision.

Secure the Impella catheter near the insertion site with commercial catheter locks and secure both sides of the red Impella plug.

Note: Do not clean the red Impella plug with alcohol or alcohol-based products.

Impella Device Indication and Safety Information

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 <https://www.heartrecovery.eu/safety-information>

- or -

Scan the code to learn more



ABIOMED, Inc.
22 Cherry Hill Drive
Danvers MA 01923 USA
Phone: +1 978-646-1400
Fax: +1 978-777-8411
marketing@abiomed.com



Abiomed Europe GmbH
Neuenhofer Weg 3
52074 Aachen
Germany
Phone: +49 (0) 241 8860-0
Fax: +49 (0) 241 8860-111
europe@abiomed.com



Clinical Support Center
24 hours, 7 days a week:
+800 022 466 33 (EU)

www.heartrecovery.eu