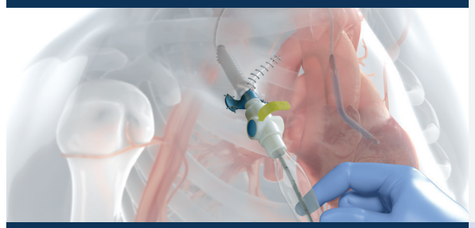
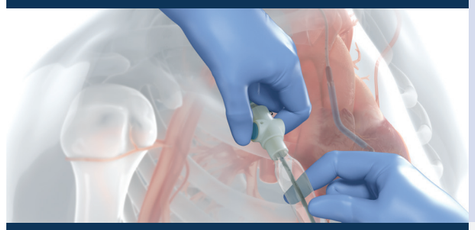
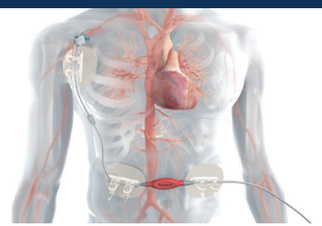
SURGICAL STEP	RECOMMENDATION
11. Confirm security of Impella catheter 	Remove the pin on the catheter anchor to lock the catheter into position. If there is still excess slack, press and hold the anchor button, remove the excess slack, and release the anchor button.
12. Adjust catheter position, if necessary 	Reposition the catheter as necessary.
13. Finish procedure and secure Impella with catheter locks 	Before leaving the procedural suite, when the pump access site is above the diaphragm, secure the catheter externally with a fixation point on either side of the red plug. Catheter fixation accessory may be used to assist in 3-point external fixation of the pump catheter to the patient body with an additional securement near the catheter anchor.

For more information on Impella 5.5 with SmartAssist, please visit the Impella education library at: HeartRecovery.com/education.

This guide is intended to be an educational tool and does not replace the Instructions for Use (IFU) manual.

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.com/en-us/important-safety-information

IMP-4476 v2

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STEP-BY-STEP GUIDE

Axillary Insertion

Impella 5.5® with SmartAssist® heart pump

The Impella 5.5 with SmartAssist heart pump is designed for surgeons with full forward flow and intelligent patient management. The Impella 5.5 heart pump is approved for use in 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-implanted 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.

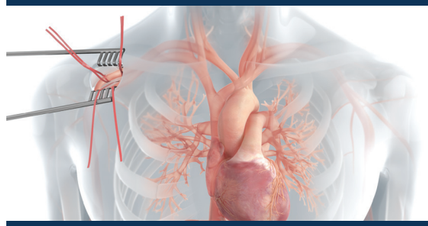
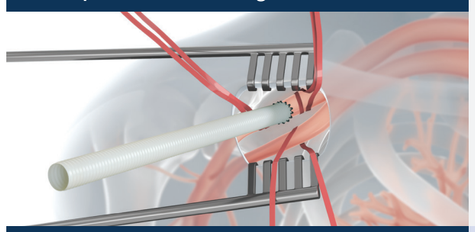
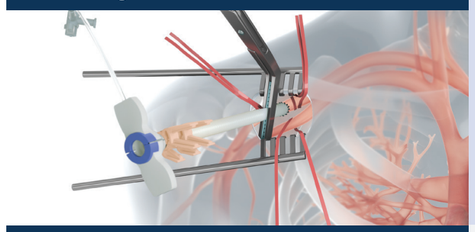
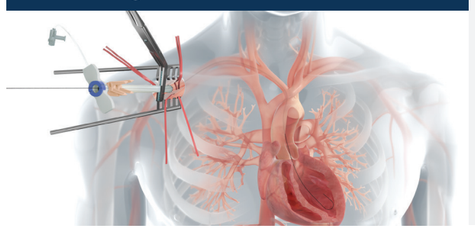
- **Full Hemodynamic Support –** Delivers peak flows up to 5.5 L/min
- **Ease of Insertion –** Optimized pump design & rigid cannula enhance deliverability & torque response
- **Ease of Use –** New intuitive catheter lock & pre-attached sterile sleeve enhance ease of use
- **Confident Positioning –**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

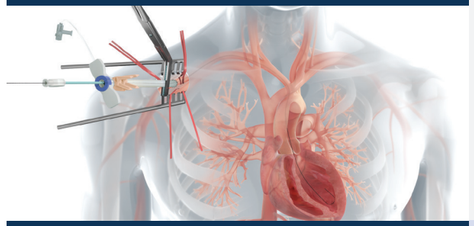
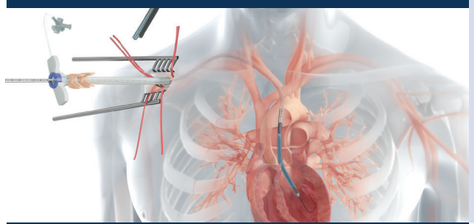
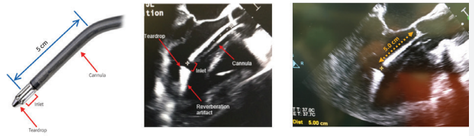
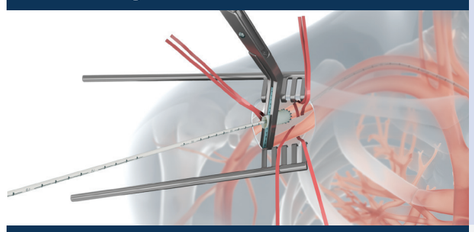
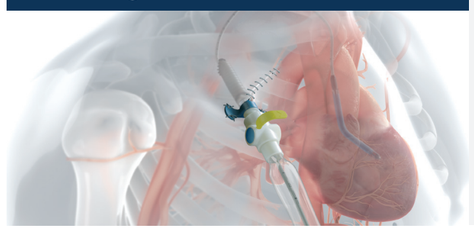
ABIOMED

Axillary Insertion

Impella®

Impella 5.5® with SmartAssist® Heart Pump

PROCEDURE STEP	RECOMMENDATION
1. Assess vessel size 	Isolate and expose the axillary artery and obtain control via proximal and distal vessel loops.
2. Create arteriotomy 	Attach a 10 mm diameter x 20 cm long vascular graft to the axillary artery using a standard end-to-side anastomosis. NOTE: Abiomed recommends using a Hemashield Platinum graft and recommends using at least a 60-degree bevel on the end of the graft to facilitate passage of the rigid motor housing into the artery.
3. Prepare and attach the graft 	Clamp the graft with a vascular clamp just above the anastomosis and loosen the vessel loops to allow blood to flow into the graft to assess for hemostasis at the anastomosis.
4. Secure graft and insert sheath 	Insert the introducer into the graft and secure it with one (1) provided graft lock. To place the graft lock, open it and place it between the retainers and the hub on the introducer to prevent the introducer from sliding out of the graft. NOTE: If a graft other than the Hemashield Platinum is used, 2 graft locks may be required to maintain hemostasis between the graft and the introducer.
5. Advance guidewire 	Remove the vascular clamp on the graft and insert a 0.035 inch diagnostic guidewire with a 4–6 Fr diagnostic catheter into the introducer, taking care to place the wire and catheter in the center of the hemostatic valve. Advance the guidewire and catheter into the left ventricle. Remove the diagnostic guidewire and exchange it for a stiff 0.018 inch placement guidewire. With the 0.018 inch placement guidewire properly positioned in the left ventricle, remove the diagnostic catheter.

PROCEDURE STEP	RECOMMENDATION
6. Lubricate valve 	Administer heparin and achieve ACT of at least 250 seconds. Remove the protective sleeve on the provided 8 Fr silicone-coated lubrication dilator, being careful to avoid getting silicone on your hands. Insert the dilator into the introducer over the 0.018 inch placement guidewire to coat the hemostatic valve with silicone oil to facilitate insertion of the Impella Catheter through the hemostatic valve assembly. Once fully inserted, remove the dilator, keeping the 0.018 inch placement guidewire in place.
7. Place Impella 5.5 catheter 	Clamp the graft with a vascular clamp just above the anastomosis to avoid blood loss through the pump cannula during insertion through the valve. While maintaining guidewire position, backload the Impella Catheter onto the 0.018 inch placement guidewire and advance the catheter over the guidewire through the introducer into the graft such that the entire pump cannula and motor housing resides in the graft and only the catheter shaft is seen exiting the valve.
8. Confirm positioning 	Remove the vascular clamp and continue inserting the Impella Catheter into the aorta. Continue advancing across the aortic valve using fluoroscopic imaging to properly position the cannula bend at the aortic valve annulus, placing inlet approximately 5cm deep into ventricle. Remove the placement guidewire and initiate Impella Catheter support.
9. Trim the graft 	Clamp the graft adjacent to the axillary artery with a soft jawed vascular clamp or have an assistant apply digital pressure to control bleeding at the base of the graft so that the introducer can be removed and the graft shortened. Slide the introducer fully out of the graft prior to peeling it away. To peel the introducer off the catheter shaft, crack the hub by applying pressure to the thumb tabs and then peel the sheath off the catheter.
10. Secure graft to suture hub 	Trim any excess graft and slide the blue suture hub into the graft. Using heavy silk suture, secure the graft around the blue suture hub so that the position of the Impella Catheter can still be adjusted. The wound should be closed over the trimmed graft with the end of the blue suture hub clearly visible. Anchor the hub securely to the skin.