

# Operating Room Quick Reference Guide

## Impella® 5.5 with SmartAssist®

This Impella 5.5 Quick Reference Guide summarizes key steps for safe and effective use of the Impella 5.5 with SmartAssist. This document is not a substitute for the full IFU, these highlights reinforce best practices for insertion, management, and daily care.

### Pre-Insertion

- For live support, call the Clinical Support Center number 1-800-422-8666 or contact your local Abiomed Clinical Consultant

Below, find best practice guidance for each insertion technique:

- Axillary Access:** Ensure vessel size and tortuosity/condition appropriate for insertion (7mm vessel) via CTA or Ultrasound if feasible
- Direct Access:** Ensure incision template is used during direct aortic placement. Identify 7cm beyond the plane of the aortic valve for 10mm graft placement

- Hand off the the end of the white connector cable and extend straight to the Automated Impella Controller (AIC). Lay it flat on the table to remove any torque in the system

- Ensure pump is primed with heparinized D5W (25 U/mL) or sodium bicarbonate (25 or 50 mEq/L)\* \*Sodium bicarbonate is the preferred purge solution where heparin is of concern due to HIT or bleeding. Physician discretion on concentration

- Prime the pump for approximately 15-20 minutes prior to insertion

- Confirm purge solution exiting motor/outflow



Impella Sidearm Retainer\*

\*No alcohol or alcohol-based cleaning solutions allowed on the purge sidearm (cover if needed)



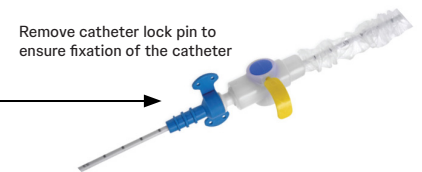
### Insertion

- To avoid the inflow being directed towards the mitral apparatus or posterior wall, torque the catheter clockwise when the inflow is in the LVOT and still on the wire. Then continue to advance. Do NOT utilize the red plug to torque the catheter

- Confirm via TEE the cannula bend should be at the aortic valve annulus, approximately 5cm deep into ventricle

- When starting the pump, slowly ramp up P-Levels to desired setting

- Should re-positioning be needed after the blue suture hub is in place, ensure the angle of entry is maintained and catheter is straight



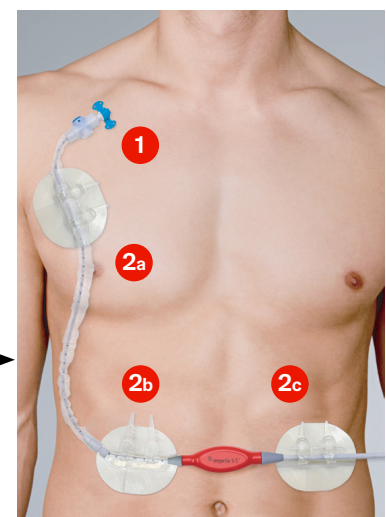
Remove catheter lock pin to ensure fixation of the catheter

### Prior to leaving OR

- Confirm the yellow catheter lock pin is removed from the catheter lock unit

- Confirm three-point external fixations in position

- During fixation adjustments or bathing, avoid using alcohol or alcohol-based products on the purge sidearm



# Intensive Care Unit Daily Management Quick Reference Guide

## Impella® 5.5 with SmartAssist®

This Impella 5.5 Quick Reference Guide summarizes key steps for safe and effective use of the Impella 5.5 with SmartAssist. This document is not a substitute for the full IFU, these highlights reinforce best practices and common pitfalls to avoid during insertion, management, and daily care.

### General ICU management

- Purge fluid (D5W with heparin 25U/mL or sodium bicarbonate is recommended\*\*)
  - \*\*D5W with Heparin 25 u/mL or 50 u/mL is acceptable. Continue to ensure purge fluid follows recommendation of D5W with Heparin 25 u/mL or Sodium Bicarbonate
- Confirm blue suture hub and anchoring mechanism or catheter lock unit is secure every shift change
- Chart cm marking on the Impella catheter closest to the catheter lock unit daily
- Chart urinary output and color, document hemodynamics, and assess right heart function
- Assess for adequate preload and right heart function if frequent suction alarms
- Alarms should be addressed immediately. Call CSC or your local Abiomed Clinical Consultant for support\*
- During fixation adjustments or bathing, avoid using alcohol or alcohol-based products on the purge sidearm



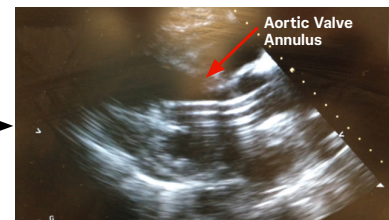
### Additional Considerations for Impella 5.5 Patients

- Ensure catheter fixation follows good placement practices. See reference photo above
  - Re-check Impella position when patient enters ICU, verify the position using echocardiography (TEE or TTE) using the recommended views. Ensure the inlet is ~5 cm to aortic valve annulus and that the inlet is free of intracardiac structures
  - If the Impella 5.5 needs to be re-positioned, maintain the angle of entry and remove catheter from external fixation prior to re-positioning, re-secure after re-positioning is complete following the same method of 3-point fixation
  - Prior to ambulation confirm catheter lock unit is secure and perform an echo to confirm inflow is 5cm below aortic valve annulus
  - For any Impella related concerns, including alarm management and purge management contact the Clinical Support Center which is available for 24/7 support



**\*Inlet position on the Impella 5.5 is 5cm from annulus**

\*Echocardiography is recommended for position adjustment.  
Recommended view:  
TEE – Mid Esophageal Long Axis  
TTE – Parasternal Long Axis



**Bend at valve annulus**



#### Indication & 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: [heartrecovery.com/isi](http://heartrecovery.com/isi)



Learn more visit:  
[www.heartrecovery.com](http://www.heartrecovery.com)  
Johnson & Johnson  
Email: [AbiomedCS@its.jnj.com](mailto:AbiomedCS@its.jnj.com)  
Tel: 1-800-422-8666



**1-800-422-8666**  
• 24/7 Impella clinical & technical expertise  
• ICU patient check-in & proactive daily monitoring  
• Patient transfer notification