



Recommendations for Avoiding Iatrogenic LV Perforation with the Impella Heart Pumps

What's New

Abiomed would like to draw attention to the importance of following the Instructions for Use (IFU) and best practices for Impella systems, particularly to reduce or eliminate the risk of iatrogenic LV perforation injury. Clinicians are cautioned to carefully position the Impella catheter and manipulate the heart in the presence of a semi-rigid cannula in the LV during an operative procedure.

Summary

There are best practices that can reduce or eliminate the risk of iatrogenic LV perforation injury with the Impella heart pumps. LV perforation is a rare complication occurring in 0.03% of Impella cases from Jan 2018 to Sep 2021. Awareness of the position of the Impella devices within the LV cavity is critical. In accordance with the Impella CP® with SmartAssist® and Impella 5.5® with SmartAssist® IFU, proper positioning of the Impella catheter is extremely important and it is worthwhile to take extra time when positioning the catheter.



Proper positioning of the Impella Catheter is extremely important and it is worthwhile to take extra time when positioning the catheter.



Physicians should exercise special care when inserting the Impella Catheter during active Cardiopulmonary Resuscitation (CPR). In addition, active CPR maneuvers may change the position of the Impella device. Check that the pump is positioned correctly in the left ventricle after CPR with echocardiography guidance.

Putting it into practice

There are different considerations for Impella 5.5 with SmartAssist and Impella CP with SmartAssist, so they will be addressed separately.

Impella 5.5 with SmartAssist in Surgical Setting

Clinicians are cautioned to carefully position the Impella catheter and manipulate the heart during an operative procedure. The risk of iatrogenic LV perforation during operative procedures exists when the heart is manipulated in the presence of any semi-rigid cannulas placed in the LV, such as the semi-rigid cannula of sump catheters or of the Impella 5.5.

While repair of an iatrogenic LV perforation is possible, maintaining awareness of the Impella 5.5 in the LV during a procedure and avoiding maneuvers that could push the Impella 5.5 through the LV wall are the best ways to prevent an iatrogenic LV perforation. Repositioning the Impella 5.5 during a procedure is simple and should be done to prevent this complication.

Best Practices for Avoiding Iatrogenic LV Perforation with Impella 5.5 are:

1. Ensuring the implant depth for Impella 5.5 remains 5 cm below the plane of the aortic valve, both for axillary implant or direct aortic implantation
2. Obtaining echo images after the patient is in the OR. This is important as the Impella 5.5 may have been placed during an earlier procedure to stabilize a patient in shock.
3. Repositioning the Impella 5.5 to the recommended position if the Impella 5.5 migrated deeper into the LV.
4. Considering the repositioning of the Impella 5.5 to a temporarily shallower position (3.5 cm) during surgery. Following the procedure, the Impella 5.5 should be returned to the usual 5 cm depth and resecured with the recommended three-point fixation.

Impella CP with SmartAssist in HRPCI Setting

Awareness of the position of the Impella devices within the LV cavity is critical. With Impella CP, cardiologists engrossed in high-risk PCI procedures should nevertheless monitor pump position and reposition Impella CP if the pigtail has become bent after migrating deeper.

Best practices for avoiding iatrogenic LV perforation with Impella CP are:

1. Impella CP should be implanted so that the inflow is 3.5 cm below the plane of the aortic valve on a long axis echo view.
2. Once the Impella CP is placed, capturing that fluoroscopic image allows the operator to be aware if the pump dives deeper.
3. Remember to fix the catheter in place using the Tuohy-Borst valve during the procedure and note the cm markings.
4. If a deeper position is noted, the PCI should be paused (if able) and the Impella CP can be pulled back to the 3.5 cm preferred position
5. Final echo prior to leaving the procedure room should confirm position and a final check for security of the catheter is made.

In conclusion, proper positioning of the Impella catheter is extremely important. To avoid the risk of an iatrogenic LV perforation, it is recommended that physicians take extra care when positioning an Impella catheter and manipulating the heart in the presence of a semi-rigid cannula in the LV during an operative procedure.



Clinical Support Center 24 hours per day, 7 days a week:
+1 800-422-8666