

Optimal Device Performance

Concomitant Device & Line Management with Impella RP[®] with SmartAssist[®] & RP Flex[™] with SmartAssist[®]

Products Impacted

Impella [®] Product Code	Impella Product Description	IFU Reference Number
1000323	Impella RP Flex with SmartAssist	10003286
0046-0035	Impella RP with SmartAssist	0052-9013

Reason for Notification

Johnson and Johnson MedTech would like reinforce guidance in the Instructions for Use (IFU) for the Impella RP with SmartAssist and Impella RP Flex with Smart Assist for use of the pump with indwelling central venous lines or devices, particularly during the insertion, manipulation and removal of those devices.

Best Practices Related to Insertion, Manipulation or Removal of Concomitant Devices

Section 5.23: Using the Automated Impella Controller with Impella RP System Catheter (Impella RP with SmartAssist and Impella RP Flex with SmartAssist)

Guidewires, indwelling central venous lines, or devices have the potential to interact with the Impella RP with SmartAssist and Impella RP Flex with Smart Assist inlet areas during use. The following guidance is recommended:

- When inserting, manipulating, or removing guidewires, indwelling central venous lines, or devices, reduce the P-level to P-2 and use imaging guidance to limit the interaction between the distal tip of the device and the inlet area of the Impella RP/ RP Flex with SmartAssist.
- When manipulating or removing existing indwelling central venous lines or cannulas thrombus formation or depositions on indwelling central venous lines or cannulas may break free. Reduce the P-level to P-2 during manipulation or removal to reduce the affinity of potential thrombus from entering the inlet area of the Impella RP/RP Flex with SmartAssist.
- After insertion, manipulation, or removal is complete, return to previous P-level.

If the patient is maintained a low flow rate (<1.5L/min) for a prolonged period of time, increase ACT to at least 250 seconds.

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Section 2: Warnings & Cautions

Complete list can be found in Section 2 of the Impella RP with SmartAssist and Impella RP Flex with SmartAssist IFUs.



Operating the pump at a high flow rate while inserting, manipulating, or removing guidewires, indwelling central venous lines or devices poses a risk of the device tip interacting with the pump inlet. This may cause damage to the pump sensors, damage to the interacting device, or loss of support. Reduce the P-level to P-2 and use imaging guidance during insertion, manipulation and removal of guidewires, indwelling lines or devices



Anti-coagulate patients as needed to maintain recommended ACT (160-180s), in particular when indwelling central venous lines or cannulas (i.e. hemodialysis, PA catheters, ECMO) are present. ACT below this level may increase the risk of thrombus formation or deposition. If either internal thrombus forms within or external thrombus deposits in the Impella RP/RP Flex with SmartAssist, this may result in reduced flow, loss of support, or hemolysis.



Thrombus formation or deposits on indwelling central venous lines or cannulas (i.e. hemodialysis catheters, PA catheters, ECMO) may break free and enter into the Impella RP/RP Flex with SmartAssist inlet, resulting in reduced flow, loss of support, or hemolysis. Assess the risk for extraluminal thrombus on indwelling lines placed prior to initiation of support.

