

Guidance on Impella® Device Implantation in Small Anatomies

Products Impacted

Impella® Product Code	Impella Product Description	IFU Reference Number
0048-0003	Impella CP® with SmartAssist®	0048-9007
1000100	Impella 5.5® with SmartAssist®	10003049

Reason for Notification

Johnson & Johnson MedTech has expanded the indications for the Impella 5.5 with SmartAssist and Impella CP with SmartAssist heart pumps for use in pediatric patients with symptomatic cardiogenic shock.

Additions to the IFU(S)

In addition to adult patients, the Impella CP with SmartAssist Catheter is now approved as a temporary ventricular support device for treatment of cardiogenic shock in **pediatric patients ≥ 52 kg,*** and the Impella 5.5 with SmartAssist Catheter is now approved as a temporary ventricular support device for treatment of cardiogenic shock in **pediatric patients ≥ 30 kg.***

Impella CP with SmartAssist		Impella 5.5 with SmartAssist	
Indication for Use	Cardiogenic Shock*	Indication for Use	Cardiogenic Shock*
Duration of Support	≤ 4 days	Duration of Support	≤ 14 days
Pediatric Weight Requirement	≥ 52 kg	Pediatric Weight Requirement	≥ 30 kg

**Full Indication for Use details can be found in Section 1.1 of the Impella CP with SmartAssist and Impella 5.5 with SmartAssist IFUs.*

IFU Warnings

Complete list can be found in Section 2 of the Impella CP with SmartAssist and Impella 5.5 with SmartAssist IFUs.

IMPELLA CP WITH SMARTASSIST



- During worst-case testing for this device, ethylene oxide residual levels exceeded the allowable limit for patients weighing under 52 kg and thus the device could pose a carcinogenic risk when used in these patients.

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IMPELLA 5.5 WITH SMARTASSIST



- During worst-case testing for this device, ethylene oxide residual levels exceeded the allowable limit for patients weighing under 30 kg and thus the device could pose a carcinogenic risk when used in these patients.

IMPELLA CP WITH SMARTASSIST AND IMPELLA 5.5 WITH SMARTASSIST



- Potential adverse events include acute renal dysfunction, aortic valve injury, bleeding, cardiogenic shock, cerebral vascular accident/stroke, death, hemolysis, limb ischemia, myocardial infarction, renal failure, thrombocytopenia and cardiac or vascular injury (including ventricular perforation).
- To reduce risk of cardiac injury (including ventricular perforation), physicians should exercise care when inserting the Impella Catheter in patients with complex anatomy. This includes patients with known or suspected: decreased ventricular cavity size, ventricular aneurysms, congenital heart disease or compromised cardiac tissue quality in the settings of acute infarction with tissue necrosis.

References for Positioning

KEY ANATOMICAL FEATURES

Imaging to evaluate insertion and fit considerations is recommended prior to insertion for patients with small and/or complex anatomies.

Anatomical Structure	Fit Assessment
Minimal Arterial Access Vessel Diameter	Impella CP with SmartAssist: • Femoral artery > 5 mm Impella 5.5 with SmartAssist: • Axillary Artery > 7 mm
Aortic arch characteristics	• Assess morphology as variations may impact device navigation and positioning • For direct insertion ensure graft can be placed at least 7 cm from the aortic valve annulus
Left (Systemic) Ventricular Cavity Size	Evaluate the length of the apex to the aortic valve • Impella CP with SmartAssist minimal length: 8.5 cm • Impella 5.5 with SmartAssist minimal length: 6.0 cm

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Left (Systemic) Ventricular Cavity Size

Optimal device placement:

- Outlet should be well above the aortic valve annulus
- Inlet should be in the midventricular cavity angled towards the apex away from the papillary muscle, mitral valve and subannular structures
- Impella CP with SmartAssist inlet to aortic valve annulus = 3.5 cm
- Impella 5.5 with SmartAssist inlet to aortic valve annulus = 5 cm

Ascending Aorta

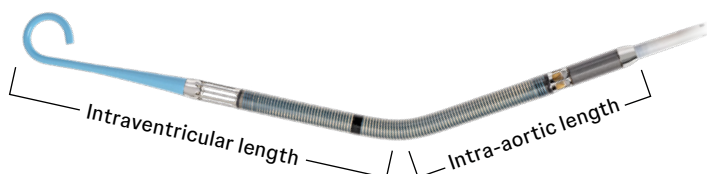
Evaluate the length of the ascending aorta from the aortic valve annulus to the arch

- Impella CP with SmartAssist minimal length: 7.0 cm
- Impella 5.5 with SmartAssist minimal length: 6.4 cm

Additional considerations: calcification and plaque at or above the access site.

Device Delivery and Fit Requirement

IMPELLA CP WITH SMARTASSIST CATHETER DIMENSIONS



Impella CP with SmartAssist	Measurements
Intraventricular Length Tip of pigtail to radiopaque marker	8.5 cm
Intra-aortic length Radiopaque marker to motor	6.7 cm
Cannula circumference	14 Fr
Cannula angle	145°
Catheter length	117 cm

IMPELLA 5.5 WITH SMARTASSIST CATHETER DIMENSIONS



Impella 5.5 with SmartAssist	Measurements
Intraventricular Length Tip of inlet to bend in cannula	6.0 cm
Bend in cannula to distal motor	6.4 cm
Cannula circumference	21 Fr
Cannula angle	145°
Catheter length Axillary insertion only	70 cm

DISTAL CATHETER DIMENSIONS



Impella CP with SmartAssist:
13 Fr x 12 cm repositioning sheath



Impella 5.5 with SmartAssist:
Insertion through graft only

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Mitigating the Risk of Hemolysis With Proper Positioning

Obstructions create tight passages – speed flow – increase their stresses.

Inflow

Can become obstructed by ventricular structures.

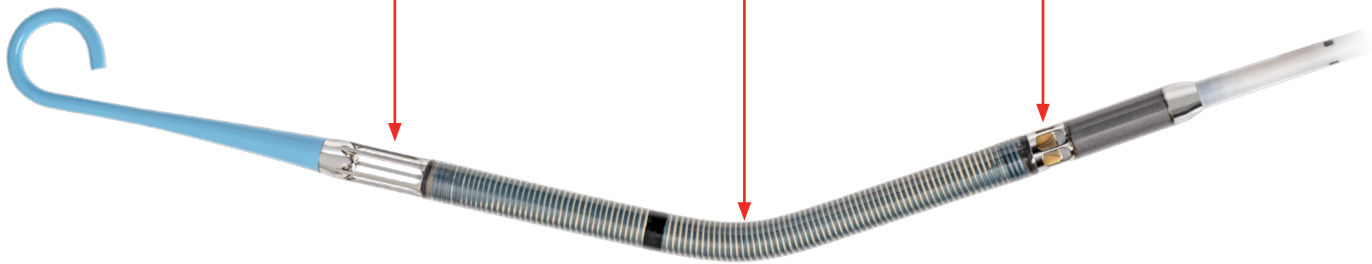
To maintain flow rate, blood will travel faster to enter unobstructed windows.

Within Cannula

Obstruction within pump (clot, fiber, etc.) creates narrowing of cannula and small passages for blood to pass through.

Outflow

If obstructed by aortic valve or aortic wall, blood will exit pump at higher speeds and will make contact with obstructing structures.



Impella CP with SmartAssist Catheter shown for reference

