

Shockwave® Impella® Interaction

Products Affected

Impella Product Code	Impella Product Description	UDI-DI	IFU Reference Number
0048-0003	Impella CP® with SmartAssist®	00813502011258	0048-9007
0550-0008	Impella 5.5® with SmartAssist®	00813502011531	0550-9002
1000100	Impella 5.5® with SmartAssist®	00813502012828	10003049

Reason for Notification

Abiomed has determined that there is a risk of optical sensor damage in Impella products as listed above when used concurrently and in close proximity with Shockwave Coronary IVL Catheter. Placement Signal Not Reliable alarm may occur and subsequently disable pump position monitoring. Loss of the placement signal does not impact Impella hemodynamic support.

New Caution Added to IFU

Use with Shockwave Coronary Intravascular Lithotripsy (IVL) Catheter at a distance of less than 20 mm between the optical sensor and IVL device may interfere with or damage the Impella optical sensor. Prior to IVL therapy pulsing, physicians should assess and verify this distance. If the placement signal is not displayed, monitor patient hemodynamics and confirm Impella position with imaging and motor current pulsatility. Loss of the placement signal does not impact Impella hemodynamic support.

Addition to IFU Section 7: Patient Management Topics (CP with SmartAssist, 5.5 with SmartAssist):

Shockwave Coronary Intravascular Lithotripsy (IVL) Catheter

The pressure waves emitted from a Shockwave Coronary Intravascular Lithotripsy (IVL) Catheter may interfere with or damage the optical pressure sensor when the Shockwave Coronary IVL device is less than 20 mm from the Impella optical sensor. Best practices to maintain adequate distance between the Shockwave Coronary IVL device and Impella optical sensor include optimal positioning of the Impella catheter with the bend of the cannula located at the aortic valve annulus. Prior to pulsing, physician users should ensure the shortest distance from the Shockwave Coronary IVL device to the Impella optical sensor is > 20 mm.

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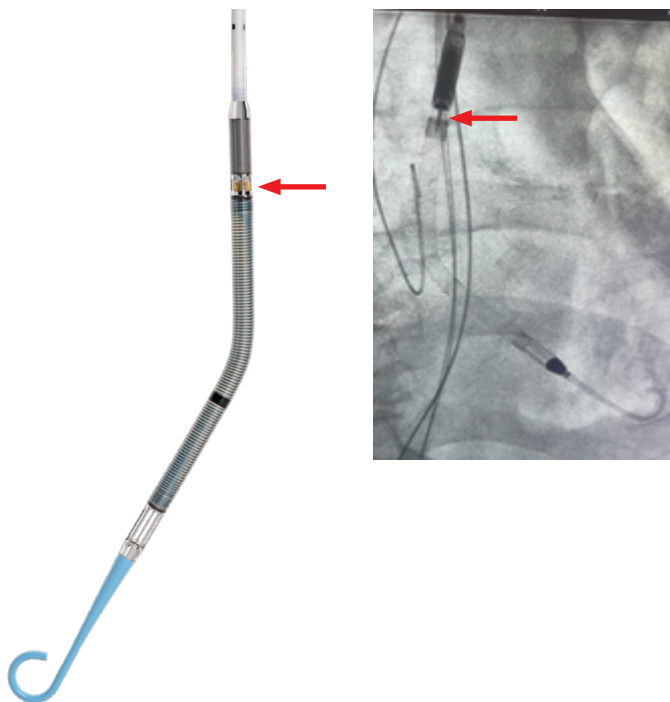


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If the placement signal is not displayed, monitor patient hemodynamics and confirm Impella position with imaging and motor current pulsatility. Placement Signal Not Reliable alarm may occur and subsequently disable position monitoring. Loss of the placement signal does not impact Impella hemodynamic support.

Reference for location of optical sensor in Impella devices

Impella CP® with SmartAssist®



Impella 5.5® with SmartAssist®

