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URGENT MEDICAL DEVICE CORRECTION (NOTIFICATION)

Update to Instructions for Use

Dear Valued Customer,

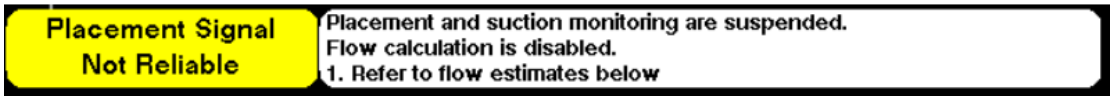
Abiomed, Inc ("Abiomed") has initiated a device correction (notification) to inform you of updates that are being added to the Instructions for Use (IFU) for all Impella products listed below. This is not a product removal.

Impella Product Code	Impella Product Description	UDI-DI
0048-0003	Impella CP® with SmartAssist®	00813502011258
0550-0008	Impella 5.5® with SmartAssist®	00813502011531
1000100		00813502012828

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.

Example of a "Placement Signal Not Reliable" alarm that may occur:



No product design or manufacturing issues are related to this potential interaction, and hemodynamic support will **not** be affected as a result of optical sensor damage. Abiomed will modify the IFUs for the Impella products listed in the table above to inform users of this risk.

A complaint review from January 1, 2021 through June 14, 2024 has identified optical sensor damage in 0.43% of cases during Shockwave Coronary IVL Catheter use. No adverse events have been reported due to this interaction at this time.

US FDA has reviewed the IFU modifications included in Attachment 1 of this letter. The modifications include additions to Cautions section and to Section 7: Patient Management Topics. Refer to Attachment 1 for IFU Modification details.

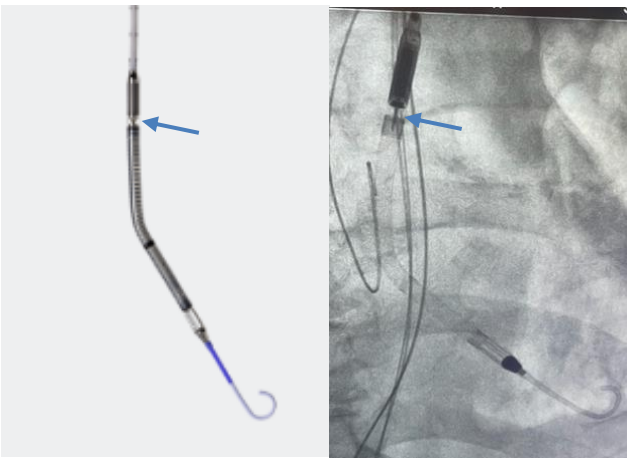
RECOMMENDATIONS:

Product in hospital inventory may continue to be used.

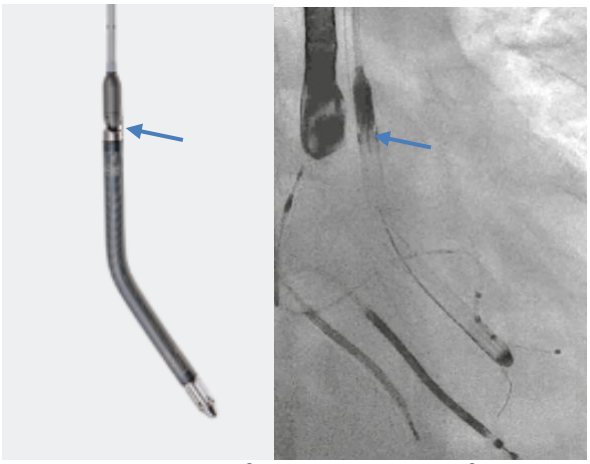
Abiomed recommends the user to maintain adequate distance (> 20 mm) between the Shockwave Coronary IVL Catheter and Impella optical sensor and include optimal positioning of the Impella catheter with the radiopaque marker band located at the aortic valve annulus.

If optical sensor failure occurs, monitor patient hemodynamics and confirm Impella positioning with imaging. The pump will still operate without placement or suction monitoring or alarm notifications.

Reference for location of optical sensor in Impella devices



Impella CP® with SmartAssist®



Impella 5.5® with SmartAssist®

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Product is NOT being removed from the field and does not need to be returned.
- Review, complete all fields, sign, and return the business response form (BRF) provided to impacted customers and sent it to Abiomed2860@sedgwick.com.
- Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products).
- If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.
- Post a copy of this notice in a visible area for awareness of this field safety notice.
- As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact your local clinical field staff. Thank you for your cooperation.

Attachments:

Attachment 1 – IFU Modification Details

Attachment 1 – IFU Modification Details

New Caution (CP with SmartAssist, 5.5 with SmartAssist):

- 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 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 radiopaque marker band 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 $\geq$ 20 mm.

  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.