Johnson&Johnson MedTech

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URGENT MEDICAL DEVICE CORRECTION (NOTIFICATION)

Update to Instructions for Use

Impella Product Code	Impella Product Description	UDI-DI
0046-0035	Impella RP® with SmartAssist®	00813502011869
1000323	Impella RP Flex™ with SmartAssist®	00813502012811

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT WHICH IS THE SUBJECT OF THIS NOTICE

Dear Valued Customer,

Please be advised that Abiomed, Inc ("Abiomed") has initiated a device correction (notification) to inform you of updates to the Instructions for Use (IFU) for the Impella products listed above. Product is not being removed and hospital inventory may continue to be used.

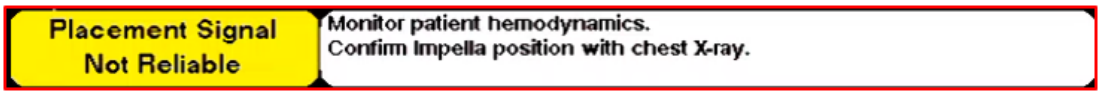
REASON FOR NOTIFICATION:

Abiomed is reinforcing that there is a risk of potential interaction between the tip of guidewires, indwelling central venous lines or devices and inlet of the Impella pumps listed above during the insertion, manipulation, and removal of those devices. The interaction may result in optical sensor damage, temporary pump stop, or permanent pump stop.

A complaint review from July 13, 2021 through October 25, 2024 identified 0.51% rate of reported device interaction with the inlet. Optical Sensor damage was reported in 0.43% of use cases due to physical contact with other devices. In rare occasions the pump flow of the Impella RP pump is also affected by device interaction with the inlet. Temporary pump stops are rare at a rate of 0.13% use cases and permanent pump stops are very rare at 0.09% of use cases. Investigations to date have not identified product design or manufacturing issues contributing to these events.

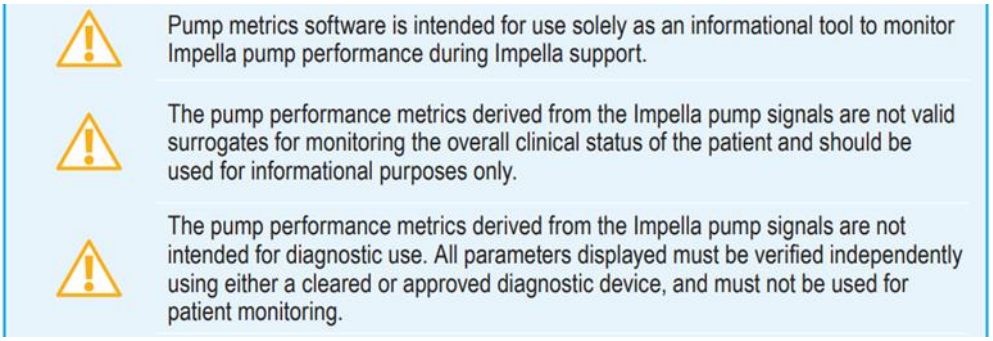
The optical sensor is intended as an informational tool on the Impella RP® with SmartAssist® and Impella RP Flex™ with SmartAssist® pumps and is not used for any positioning algorithms/alarms or flow calculations. Optical sensor damage results in a Placement Signal Not Reliable (PSNR) alarm and loss of Central Venous Placement (CVP) Signal, Pulmonary Artery (PA) Placement Signal, and Pulmonary Artery Pulse Index (PAPi) metrics.

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



However, hemodynamic support and Impella position are not affected as a result of optical sensor damage and no patient injuries have been reported due to this optical sensor damage.

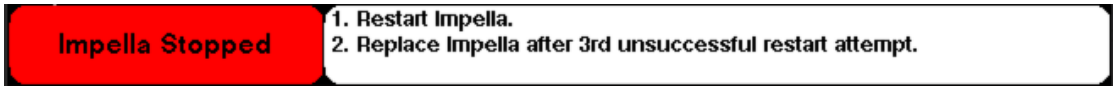
As per current IFUs, hemodynamic measurements should always be verified independently using either a cleared or approved diagnostic device, irrespective of optical signal loss. See below excerpt.



Impella RP Flex™ with SmartAssist® IFU (10003286 rF)
Impella RP® with SmartAssist® IFU (0052-9013 rF)

In the event of a pump stop, the system immediately and automatically attempts to restart the pump and return to the previously set P-level, and an "Impella Stopped" alarm will be displayed. The user may also manually restart the pump by selecting an appropriate P-level to meet the patient's hemodynamic needs.

Example of the "Impella Stopped" alarm that may occur:



Damage to the guidewire, indwelling central venous line or other device may be incurred from the interaction with the Impella RP inlet. Users should assess if a new guidewire, indwelling central venous line or other device is required.

US FDA is aware of this correction, and the intended IFU modifications included in Attachment 1 of this letter. The modifications include additions to the Warnings section and to Section 5: Using the Automated Impella Controller with Impella RP System Catheter. Refer to Attachment 1 for IFU Modification details.

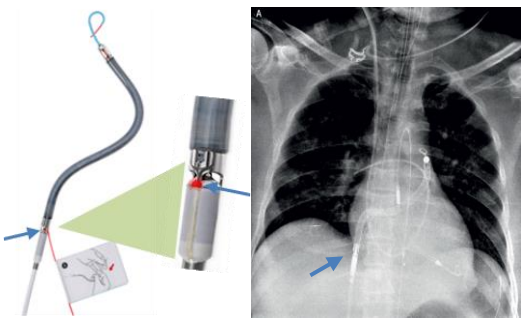
RECOMMENDATIONS:

Product is not being removed and hospital inventory may continue to be used.

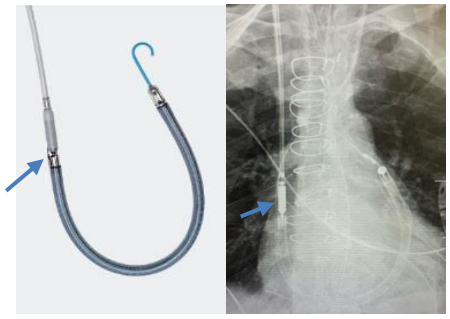
It is recommended that users lower the pump flow level to P-2 and use imaging guidance when inserting, manipulating, or removing any guidewires, indwelling venous lines or devices to reduce the potential for interaction of the device tip with the pump inlet.

If optical sensor damage occurs and Placement Signal Not Reliable (PSNR) alarm is displayed no additional actions are required. Hemodynamic support and Impella position are not affected and can be monitored as part of routine patient/pump management. In addition, calculated flow and suction monitoring are also unaffected when an optical sensor PSNR alarm is displayed.

Reference for location of optical sensor in Impella devices



Impella RP® with SmartAssist®



Impella RP Flex™ with SmartAssist®

In the event of a pump stop, follow the displayed prompts of the "Impella Stopped" alarm.

Damage to the guidewire, indwelling central venous line or other device involved in the unintended interaction should be evaluated, and users should assess if a new device is required.

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 provided business response form (BRF) to Abiomed6329@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.

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- 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 as per below instructions:
  - Complete and submit the report online: www.fda.gov/medwatch/report.htm or
  - Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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 onemd-field-actions@its.jnj.com or your local clinical field staff. Thank you for your cooperation.

Attachments:

Attachment 1 – IFU Modification Details

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Attachment 1 – IFU Modification Details

New Warning (Impella RP with SmartAssist and Impella RP Flex with SmartAssist):

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 central venous lines or devices.

Addition to Section 5: Using the Automated Impella Controller with Impella RP System Catheter (Impella RP with SmartAssist and Impella RP Flex with SmartAssist)

Insertion, manipulation, or removal of concomitant devices

Guidewires, indwelling central venous lines, or devices have the potential to interact with the Impella RP (Flex) with SmartAssist inlet area 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 (or Impella RP Flex) with SmartAssist.
- After insertion, manipulation, or removal is complete, return to previous P-level.