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<FIRST/SECOND/THIRD> ATTEMPT

URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION)

SUBJECT DEVICES:
This information concerns all lots for the following Impella heart pumps:

Impella® 2.5	Impella® 5.0	Impella® 5.5 with Smart Assist
Impella® LD	Impella® CP	Impella® CP with Smart Assist

Date: <Date>

<Customer Name>
<Address>

Dear Valued Customer,

This letter is to notify you about additional information that Abiomed, Inc ("Abiomed") is providing for the continued safe use of Impella heart pumps in patients with a transcatheter aortic valve replacement (TAVR).

REASON FOR NOTIFICATION

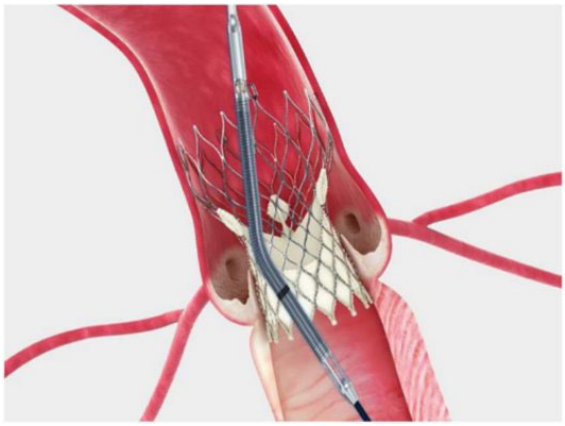
There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a TAVR resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system.

The outflow struts of the TAVR can enter the outlet opening of Impella and damage the impeller (see figure below) during repositioning of the Impella while the impeller is spinning. This interaction while the impeller is spinning can result in fracture of the impeller material. Although no events have been identified, systemic embolization of the fractured impeller material is a possibility.

This complication has been observed in 0.7% of patients (27 complaints) with TAVR who were supported by the Impella system from 2016 to present. 25 out of 27 complaints involved the Impella CP. For a patient with TAVR who needs hemodynamic support, clinicians should factor this risk into the risk benefit analysis and are cautioned to position the Impella system carefully as directed in this notification.

This risk of interaction is increased for oversized or under expanded frames with the distal ends not flush with the aortic wall, resulting in the distal stent structures oriented in such a way as to potentially enter the outflow window and allow contact of the end of the stent with the spinning impeller.

Abiomed is revising the IFUs for the subject pumps to include the recommendations related to this potential interaction. This is the first communication regarding this issue in the United States market. Abiomed previously issued a Field Safety Notification to the European Market and updated the European IFU.



RECOMMENDATIONS:

Clinicians are cautioned to position the Impella system carefully in patients with TAVR, and to be aware of this potential interaction. In this situation, clinicians should avoid repositioning while the device is spinning and should turn the device to P0 during repositioning or any movement that could bring the outlet windows into proximity to the valve stent structures.

If there is low flow observed in a patient implanted with a TAVR while on Impella heart pump support, you should consider damage of the impeller and replace the Impella pump as soon as possible.

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 attached business response form (BRF) on the last page of this letter to the Recall Coordinator identified in this document.
- 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 (Shashi Thoutam) directly at +1(734) 262-6255 and/or your local clinical field staff. Thank you for your cooperation.

Respectfully,

Shashi Thoutam
Sr. Manager, Global Quality Systems
ABIOMED. Inc.
22 Cherry Hill Drive
Danvers, MA 01923
Tel: +1 (734) 262-6255
sthoutam@abiomed.com

Attachments: Business Reply Form

URGENT MEDICAL DEVICE CORRECTION (NOTIFICATION)

Business Reply Form (BRF)

Response is Required

Recall Coordinator
<Customer Address>

By Signing this form, I am confirming that I have read and understand the correction (notification) instructions provided in this letter dated <DATE>.

☐ Yes

Acknowledgement Signature		**Date**	
Print Name		**Telephone**	
Hospital Name			
Email			
Comments:			

Please scan and email completed response to recallcoordinators@abiomed.com or mail to the following address:
Shashi Thoutam (Sr. Manager, Global Quality Systems)
ABIOMED, Inc.
22 Cherry Hill Drive Danvers MA, 01923