Abiomed, Inc.
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www.abiomed.com

FSN Ref: 2025-FSN-000108 FSCA Ref: 2025-FA-000108

Date: 2025-09-25

URGENT Field Safety Notice
AIC Purge Retainer Fixation Correction.

For Attention of*: Automated Impella Controller (AIC)

Contact details of local representative (name, e-mail, telephone, address etc.)*
Mariano Santos Senior Manager, Commercial Quality Msant169@its.jnj.com +49 1511 8928039

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	All Automated Impella Controller (AIC)
1.	2. Commercial name(s)*
	Automated Impella Controller (AIC)
1.	3. Primary clinical purpose of device(s)*
	The Automated Impella Controller provides three functions to the operation of the Impella Catheter: • The controller provides an interface for monitoring and controlling the function of the Impella Catheter. • The controller provides a purge fluid to the Impella Catheter. • The controller provides backup power when the Impella Ventricular Support Systems are operated away from AC power.
1.	4. Device Model/Catalogue/part number(s)*
	0042-0010; 0042-0040; 0042-0000. (not all models apply to all countries)
1.	5. Software version
	All AIC Software version.
1.	6. Affected serial or lot number range
	Refer to Customer Reply form (Page 7) for list of impacted AIC serial numbers.
1.	7. Associated devices
	All Impella heart pump models are run by the Automated Impella Controller (AIC). The AIC also drives the Purge Cassette to provide purge fluid to the Impella pumps.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Abiomed identified a design change to correct the AIC purge retainer fixture that will be implemented through device servicing at the Abiomed Service Center. This design change involves the addition of a third mounting screw for the purge retainer, improving fixation. Abiomed has decided to initiate a Field safety corrective action for Automated Impella Controllers (AICs) in the field related to a design change that improves the AIC purge retainer fixture and addresses potential purge retainer failures. Failures impacting purge pressure and detection of the purge disc may lead to errors, alarms, and potential interruptions in hemodynamic support when the AIC may need to be replaced. Abiomed identified a rate of 0.61% (660 complaints / 98,861 cases from February 2022 to July 2024) AIC purge pressure issues due to purge retainer failures. Currently this rate is 0.19% (105 complaints / 55,471 cases from August 2024 to June 2025). Complaints review determined that there have been no deaths and 5 serious injuries directly related to this failure. When this issue arose, it was determined that force applied during purge disc insertion/removal was determined to be a factor contributing to the purge retainer failures. Failures impacting purge pressure and detection of the purge disc may lead to errors, alarms, and potential interruptions in hemodynamic support when the AIC may

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	need to be replaced. In unusual circumstances, (i.e. purge system failure), this failure may result in a pump stop with resultant loss of hemodynamic support which is considered a life-threatening injury with the potential for permanent impairment or death. Ninety-one percent (91%) of global AIC consoles that have been serviced by Abiomed since April 2024 have been corrected with the design change, and nine percent (9%) of AIC consoles globally still require the correction. Customers with consoles that have already been corrected are not receiving this notification. If you are receiving this letter, Abiomed's records indicate you are in possession of an AIC console that requires the correction. Refer to Customer Reply form (Page 7) for list of impacted AIC serial numbers. **RECOMMENDATIONS:** To ensure continuity of care, hospital inventory can continue to be used. Abiomed has identified customers with AIC product subject to the update and will implement the applicable correction for these identified customers through device servicing at the Abiomed Service Center. Abiomed service team will contact you to coordinate the return of the device(s) to implement this update. Customers are reminded of the ongoing Abiomed AIC related field action in June 2025 for a potential Automated Impella Controller (AIC) intermittent detection issue during Impella pump transfer when the pump is connected. This purge retainer fixation correction is a different Field Safety Corrective Action. **ACTIONS TO BE TAKEN BY CUSTOMER/USER:** • Hospital inventory can continue to be used to ensure continuity of care. • Upon contact from Abiomed's field servicing team, please work with them to return the identified device(s) for the change to be implemented. Refer to Customer Reply form (Page 7) for list of impacted AIC serial numbers. • Review this notice carefully, and forward 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.
2.	2. Hazard giving rise to the FSCA*
	Health Hazard Evaluation conclusion: The identified failures in the AIC Purge Pressure Sensors present risks to the accurate measurement of purge pressure and detection of the purge disc during clinical procedures. These failures may lead to errors, alarms, and potential interruptions in hemodynamic support when the AIC or Purge retainer may need to be replaced. To address these issues, design enhancements and process changes have been implemented, including the addition of a third screw in the retainer assembly and the provision of guidance on approved cleaning methods. The potential patient risk

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	associated with this issue is being addressed by the design improvement which is being implemented through annual preventative maintenance (PM) executed by the field service and manufacturing process. In case of failure, the AIC may need to be swapped out for a backup unit, and physicians must use clinical judgment to ensure patient safety during the transition. Exposure to the AIC purge pressure sensor and failures may result or can be reasonable expected to result in a user inconvenience and a period of inadequate hemodynamic support which is considered to be a reversible injury; only under unusual circumstances (ex :purge system failure), exposure may result in a pump stop with resultant loss of hemodynamic support which is considered a life-threatening injury with the potential for permanent impairment. A comprehensive review of clinical and case details, complaint reports, and event descriptions was conducted in all cases that were reported as death and serious injury. The assessment focused on determining whether the failure mode was directly associated with death or serious injury outcomes. The review found that none of the death reports showed sufficient evidence of a direct link to the failure. Among the 7 serious injury reports, 5 were deemed directly related due to the requirement for console exchange (severity 3). The remaining 2 reports lacked enough data to establish a clear connection. To date (July 25,2025), there have been no directly associated deaths and there have been 35 occurrences that resulted in console exchanges. While the product issue does increase the risk profile of the device, the risk is outweighed by the benefit associated with the use of the Impella system overall.
2.	3. Probability of problem arising
	Abiomed identified a rate of 0.61% (660 complaints / 98,861 cases from February 2022 to July 2024) AIC purge pressure issues due to purge retainer failures. Currently this rate is 0.19% (105 complaints / 55,471 cases from August 2024 to June 2025). Complaints review determined that there have been no deaths and 5 serious injuries directly related to this failure. When this issue arose, it was determined that force applied during purge disc insertion/removal was determined to be a factor contributing to the purge retainer failures. Failures impacting purge pressure and detection of the purge disc may lead to errors, alarms, and potential interruptions in hemodynamic support when the AIC may need to be replaced. In unusual circumstances, (i.e. purge system failure), this failure may result in a pump stop with resultant loss of hemodynamic support which is considered a life-threatening injury with the potential for permanent impairment or death.
2.	4. Predicted risk to patient/users
	Impact beyond users: No impact beyond the user.
2.	5. Further information to help characterise the problem
	Please follow instructions in section 2.1
2.	6. Background on Issue
	Abiomed has decided to issue an FSCA as part of a design change.
2.	7. Other information relevant to FSCA
	N/A

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3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations. ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other: Field service will be contacting you. ☐ None **ACTIONS TO BE TAKEN BY CUSTOMER/USER:** • Hospital inventory can continue to be used to ensure continuity of care. • Upon contact from Abiomed's field servicing team, please work with them to return the identified device(s) for the change to be implemented. Refer to Customer Reply form (Page 7) for list of impacted AIC serial numbers. • Review this notice carefully, and forward 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. **To increase awareness of these recommendations:** *** Keep the copy of this FSN together with your IFU.**	
3.	2. By when should the action be completed?	Design change will be implemented at the next service opportunity.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other: ☐ None Design change will be implemented at the next service opportunity..	
3.	5. By when should the action be completed?	Design change will be implemented at the next service opportunity.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

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4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Abiomed Inc.
	b. Address	22 Cherry Hill Drive, Danvers, MA, US
	c. Website address	www.heartrecovery.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	None
4.	10. Name/Signature	Colin McArthur Senior Director, Commercial Quality

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where Impella pumps and Automated Impella Controller (AIC) have been transferred. Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action and keep this FSN together with the existing version of the product IFU. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2025-FA-000108
FSN Date*	2025-09-25
Product/ Device name*	Automated Impella Controller (AIC)
Product Code(s)	0042-0000, 0042-0010; 0042-0040.
Serial number(s)	

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

If additional organizations are covered by your response, please ensure their details are recorded in the table on the next page.

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Complete or enter N/A
☐	I performed all actions requested by the FSN.	Complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users.	Complete or enter N/A
☐	I have a query please contact me	Enter contact details if different from above and brief description of query
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	DL-EUFSCA@its.jnj.com
Customer Helpline	+800 0 22 466 33
Postal Address	Abiomed GmbH Att. of Mariano Santos Neuenhofer Weg 3 52074 Aachen -Germany
Web Portal	www.abiomed.eu; www.heartrecovery.eu
Deadline for returning the customer reply form*	**Please return within 7 working days**

Mandatory fields are marked with *

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This Customer reply form also applies to these additional organizations:

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.