Abiomed, Inc.
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www.abiomed.com

FSN Ref: 2026-FSN-0000147 FSCA Ref: 2026-FA-0000147

Date: 2026-07-25

URGENT Field Safety Notice
Risk of Persistent Low Purge Pressure Condition

For Attention of*: Users of Impella CP Set with SmartAssist

Contact details of local representative (name, e-mail, telephone, address etc.)*
E-Mail: DL-EUFSCA@its.jnj.com **Malte Flory +49 172 4556857** **Abiomed Europe GmbH** **Neuenhofer Weg 3** **D-52074 Aachen** **Customer Service Tel.: +800 0 22 466 33**

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Temporary left ventricular mechanical circulatory support device / intracardiac circulatory assist axial-pump catheter (Impella CP platform).
1.	2. Commercial name(s)*
	Impella CP Set with SmartAssist
1.	3. Primary clinical purpose of device(s)*
	The device provides temporary left ventricular support and circulatory assistance. Indicated for high-risk PCI procedures and treatment of cardiogenic shock by unloading the left ventricle and providing hemodynamic support to allow heart recovery.
1.	4. Device Model/Catalogue/part number(s)*
	0048-0014
1.	5. Software version
	Not applicable
1.	6. Affected serial or lot number range
	Serial Numbers: 636173 – distributed in Czech Republic 499250 – distributed in Norway
1.	7. Associated devices
	Automated Impella Controller (AIC), purge cassette, guidewire, introducer kit.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Abiomed identified a manufacturing-related defect affecting a limited number of Impella CP with SmartAssist devices. This manufacturing condition can result in abnormally high purge flow requirements despite the absence of any external purge system leak. When the purge flow increases to compensate for the altered bearing condition, the system may reach the maximum allowable purge flow rate (30 mL/hr) while failing to maintain the expected purge pressure. As a result, the Automated Impella Controller (AIC) may display persistent "Low Purge Pressure" alarms and purge pressures below 300 mmHg. The issue generally presents immediately upon priming, insertion, or initiation of pump support. Field complaints show that attempted troubleshooting measures such as replacing the purge cassette, changing purge solutions, or replacing the controller console did not resolve the condition. In some cases, the only effective corrective action was replacement of the Impella pump. **Instructions to Locate affected Impella CP Sets:**

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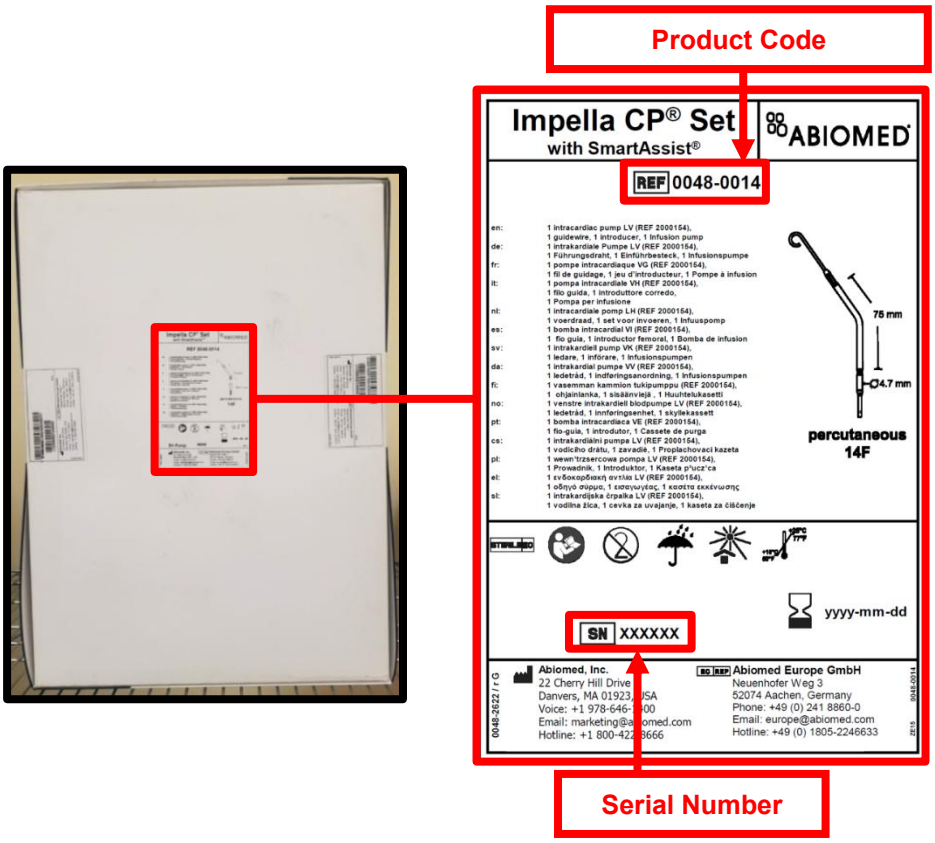
The subject devices have a label on the outer box as seen below. To identify if your units are affected by this field action, refer to the serial number (SN) on the label (red box) and check if the serial number matches the serial number(s) listed below.

Product Code	Product Description	Impacted Serial Numbers
0048-0014	Impella CP Set with SmartAssist	636173 (Czech Republic) 499250 (Norway)



ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- **Immediately identify affected devices**
  - Review inventory and stock for any affected serial numbers listed in the recall notification. Verify all Impella CP devices against the provided affected serial number list. Instructions to Locate affected devices is provided above.
- **Stop using affected devices**
  - Do not use any affected Impella CP device identified in inventory.
  - Immediately quarantine affected units to prevent inadvertent use.
- **Return affected products**
  - Please contact Abiomed to arrange the return and replacement of the pump.
- **Maintain awareness if a device is already in use**
  - The recall is limited to specific serial numbers.

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	○ If a potentially affected device is encountered clinically, users should be alert for: ▪ Persistent "Low Purge Pressure" alarms. ▪ Maximum purge flow conditions. ▪ Failure of standard troubleshooting measures (cassette exchange, controller exchange, purge adjustments). If the issue occurs, follow the applicable IFU troubleshooting guidance and consider pump exchange as clinically appropriate. • Review the information within this letter, complete all mandatory fields, sign, and return the Customer Reply Form to DL-EUFSCA@its.jnj.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. • As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the manufacturer and/or the relevant Health Authority. 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 DL-EUFSCA@its.jnj.com or your local clinical field staff. Thank you for your cooperation.
2.	2. Hazard giving rise to the FSCA*
	Exposure to the low purge pressure occurrence may result in persistent low purge pressure alarms and, in some cases, interruption or loss of mechanical circulatory support. Loss of support may lead to acute hypotension, end-organ hypoperfusion, and risk of death if not promptly corrected. The standard troubleshooting methods are ineffective and pump exchange needs to be considered.
2.	3. Probability of problem arising
	The probability of occurrence was assessed as very low. A review of global complaints from January 1, 2024 to April 12, 2026 identified the issue in 0.01% of cases (12 complaints reported out of 107,277 cases). The complaints review determined that there has been one (1) patient death where the association of the above-described issue could not be excluded due to pump exchange. There have been an additional three (3) cases where the failure resulted in the user choosing to exchange the pump, which is considered a medical intervention.
2.	4. Predicted risk to patient/users
	The severity of harm depends on the clinical situation, duration of support interruption, and patient dependence on the device. Potential patient outcomes identified in the Health Hazard Evaluation include: **User inconvenience**

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	Persistent low purge pressure alarms may require increased monitoring, troubleshooting activities, and workflow disruption without causing patient injury. **Additional clinical intervention** The issue may require purge cassette replacement, adjustment of purge solution concentration, console exchange, pump exchange, or other medical interventions to maintain patient support. **Inadequate hemodynamic support** Reduced device performance could lead to insufficient circulatory assistance, worsening patient instability, reduced organ perfusion, and clinical deterioration. **Loss of hemodynamic support** If pump stoppage occurs and support is lost, consequences may include: • Acute hypotension • Reduced end-organ perfusion • Progression of cardiogenic shock • Requirement for emergent alternative circulatory support • Permanent organ injury • Death Abiomed noted that no patient deaths or irreversible injuries have been definitively causally attributed to this failure mode; however, there have been one death where the association of the above-described issue could not be excluded due to pump exchange.
2.	5. Further information to help characterise the problem
	The issue has a reproducible complaint profile observed across multiple reports: • Low purge pressure alarms occur immediately after priming, insertion, or pump start-up. • Purge pressures remain low despite checking connections and replacing purge cassettes. • Users may observe maximum purge flow values (30 mL/hr) simultaneously with low purge pressure readings. • Console replacement typically does not resolve the issue. • Increasing glucose concentration typically does not resolve the problem. • Pump exchange generally resolves the problem. The issue is not associated with visible external leakage and may therefore be confused initially with purge cassette or controller-related problems.
2.	6. Background on Issue
	The issue originated from post-market complaints associated with Impella CP devices exhibiting high purge flow and low purge pressure conditions. During the CAPA investigation, Abiomed determined that distal bearing non-cylindricity is the root cause of the failure mode. This failure mode was not detected through manufacturing controls.

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	The identified manufacturing defect was linked to a limited, traceable population of devices. Through manufacturing record review and traceability analysis, Abiomed identified ten distributed units potentially affected by the defect and initiated a global product removal. Two of those devices were distributed in EU and are the subject of this notification.
2.	7. Other information relevant to FSCA
	N/A

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 ☐ None **Follow recommendations described in section 2.1**	
3.	2. By when the action should be completed?	As soon as possible.
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	
3.	5. By when the action should be completed?	As soon as possible.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

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	

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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	Malte Flory Senior Manager, Commercial Quality EMEA

	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 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

Mandatory fields are marked with *

1. Field Safety Notice (FSN) information	
FSN Reference number*	2026-FA-0000147
FSN Date*	2026-07-25
Product/ Device name*	Impella CP Set with SmartAssist;
Product Code(s)	Catalogue Number: 0048-0014 Serial Number: 636173 – distributed to Czech Republic 499250 – distributed to Norway

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 Malte Flory 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**

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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.