Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923 USA
Phone: 978-646-1400
Fax: 978-777-8411
www.abiomed.com

FSN Ref: P2023-0185-FSN-EN FSCA Ref: P2023-0185-FSCA

Date: 2023-05-08

Field Safety Notice
Impella 5.5 with SmartAssist heart pump

For Attention of: xxxx

Contact details of local representative (name, e-mail, telephone, address etc.)
Karsten Wallbrück / Max Eisen
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Abiomed Europe GmbH, Neuenhofer Weg 3, D-52074 Aachen

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Field Safety Notice (FSN)
Impella 5.5 with SmartAssist heart pump
Risk of purge leak

1. Information on Affected Devices	
1.	1. Device Type(s)
	The Impella 5.5® with SmartAssist® heart pump is a temporary left ventricular support pump that delivers up to 5.5 liters of blood per minute from the left ventricle into the aorta to support a patient's hemodynamic system. Abiomed is issuing a medical device recall of a subset of Impella 5.5 with SmartAssist Sets only. Our records show that your facility received one or more units of the devices subject to this recall.
1.	2. Commercial name(s)
	Impella 5.5 with SmartAssist
1.	3. Primary clinical purpose of device(s)
	The Impella 5.5 with SmartAssist heart pump is an intracardiac pump for supporting the left ventricle. It is intended for clinical use in cardiology and in cardiac surgery for up to 30 days for the following indications, as well as others:
	• The Impella 5.5 with SmartAssist is a cardiovascular support system for patients with reduced left ventricular function, e.g., post cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction. • The Impella 5.5 with SmartAssist may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome.
1.	4. Device Model/Catalogue/part number(s)
	0550-0007; distributed as pump set with model number 0550-0002
1.	5. Affected serial numbers in CH
	408363, 405946, 406378, 405469, 405947

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	Specific Impella 5.5® with SmartAssist® Sets are being recalled as result of Abiomed receiving complaints of purge fluid leaks from the purge sidearm related to the Impella 5.5 with SmartAssist pump. Investigations conducted at the time these complaints were received showed that the root causes for the increases in purge sidearm leak complaints were related to (i) damage to the purge sidearm (identified in 2019), and (ii) interaction of sodium hydrogen carbonate with the luer locking mechanism on the purge sidearm that connects to the purge cassette (identified in 2021). The integrity of the purge sidearm is critical to the delivery of the purge fluid that prevents blood ingress in the pump motor. After introducing accessories and communications relaying best practices to mitigate these issues, the complaint rate for purge leak due to sidearm damage has decreased but continues to be higher than devices with the preinstalled retainer and new yellow luer.

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	Currently, product in the field includes units with and without the preinstalled retainer and with or without the new yellow luer components.
2.	2. Hazard giving rise to the FSCA
	The function of the purge fluid is to prevent blood ingress to the motor, which is responsible for the main pumping function of the Impella pump. If a purge leak occurs, initially the system will experience low purge pressures, prompting alarms and requiring evaluation of the system. If a temporary solution to the leak is available and the pump continues to work during the time support is needed, there is no harm to the patient. In the event that the issue is not resolved, it may lead to persistent low purge pressure and purge flow and **will eventually lead to pump stop and loss of therapy**. In critical patients with need for full support, failure of support can lead to further deterioration and worsening of their critical situation.
2.	3. Probability of problem arising
	Purge leak may occur in up to 2.7% of cases using the older pump type without pre-installed retainer and new yellow luer.
2.	4. Predicted risk to patient/users
	Pump stops may occur in up to 0.3% of cases using the older pump type without pre-installed retainer and new yellow luer
2.	5. Further information to help characterise the problem
	Use of sodium hydrogen carbonate as purge fluid additive increases the likelihood of luer failure. Mechanical stress to the purge sidearm and use of alcohol-based cleaning fluids on the purge sidearm increases the likelihood of damages to the purge system. The Impella 5.5 with SmartAssist Sets with the preinstalled Sidearm Retainer and the new yellow luer are not part of this recall.
2.	6. Background on Issue
	Overall, there were 179 separate complaints received for the impacted products worldwide, thereof 165 in the USA, 12 in Germany and 2 in Switzerland. Eleven (11) complaints in the US were associated with product malfunction or serious injury considered reportable. None of the complaints in Europe lead to patient deterioration or injury .
2.	7. Other information relevant to FSCA
	All users are reminded to the correct purge solution according to the approved Instructions for Use: 5% glucose in water (5%-20% acceptable) with 25 or 50 IU heparin /ml;In the event that a patient is intolerant to heparin, due to heparin-induced thrombocytopenia (HIT) or bleeding, physicians should use their clinical judgment to assess the risks versus benefits of operating the Impella System without heparin. Initial testing has been performed with sodium hydrogen carbonate 8.4% 25 mEq in 1L Glucose 5% in water as an alternative purge solution in order to preserve pump purge performance for patients who cannot tolerate heparin in the purge. However, sodium hydrogen carbonate additive is not approved outside of the US; Impella 5.5 pumps with serial numbers listed in the attachment do not include the latest design updates to minimize the risk of failure of the yellow luer on the purge line. Avoid using sodium hydrogen carbonate additive to the purge solution for patients supported by any of these pumps. Abiomed does not endorse or recommend the use of Impella devices in any manner other than as described in the instructions for use manual. Our provision of this information in no way constitutes a recommendation for patients suffering from HIT. Physicians should use their clinical

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	judgment to assess the risk versus benefits of operating the Impella system without heparin in the purge.
	Please also follow these recommendations to further minimize the risk of purge leak and pump stop: • Prior to implant, ensure the Impella Sidearm Retainer is in place. • As per the Instructions for Use (IFU), sterilization solutions which contain isopropyl alcohol (IPA) should never be applied to the Impella sidearm and purge filter. • Purge cassette changes can be performed less frequently (purge cassettes have been tested with sodium hydrogen carbonate for 5 days).

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 Remind all users at your site to the correct purge solution according to the approved Instructions for Use: 5% glucose in water (5%-20% acceptable) with 25 or 50 IU heparin /ml.		
3.	2. By when should the action be completed?	Remind users of the IFU indicated purge solution as soon as possible. Check your site's inventory of Impella 5.5 with SmartAssist Pumps to identify pumps listed in the attached serial number listing and return the attached response form to the above listed local contact as soon as possible.	
3.	3. Is customer Reply Required?		Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Abiomed offers to exchange Impella 5.5 with SmartAssist pumps listed in the attachment. Please note that the Impella 5.5 with SmartAssist Sets with the preinstalled Sidearm Retainer and the new yellow luer are not part of this recall (removal).		

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3.	5. By when should the action be completed?	Abiomed will contact you as soon as replacement devices become available. The exchange will likely be executed between May 05, 2023 and November 30, 2023.
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. 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 Dr, Danvers, MA 01923, USA
	c. Website address	www.abiomed.com
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	4. List of attachments/appendices:	N/a
4.	5. Name/Signature	Shashi Thoutam - Sr. Manager, Global Quality Systems

	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 the potentially affected devices have been transferred. (As appropriate) 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. 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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Field Safety Notice (FSN)
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Risk of purge leak
Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	P2023-0185-FSN-EN
FSN Date*	2023-05-08
Product/ Device name*	Impella 5.5 with SmartAssist
Product Code(s)	1 0550-0007 (Sterile Pump) 2 0550-0002 (Pump Set)
Serial Number (s)	1 408363 2 405946 3 406378 4 405469 5 405947

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*	

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 and executed.	Complete or enter N/A	
☐	I have identified the following affected devices in our inventory.	1 408363 2 405946 3 406378 4 405469 5 405947	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
☐	The following affected devices have been used and are no longer in our inventory.	1 408363 2 405946 3 406378 4 405469	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No

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		5 405947 ☐ Yes ☐ No
☐	I do not have any affected devices.	Complete or enter N/A
☐	Other Action (Define):	
☐	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	Vigilance@abiomed.com
Customer Helpline	+49 (0) 1805 2246633 (EU)
Postal Address	Abiomed Europe GmbH - att. Max Eisen - Neuenhofer Weg 3 52074 Aachen Germany
Web Portal	Abiomed.com
Deadline for returning the customer reply form*	May 10, 2023

Mandatory fields are marked with *

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.