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

FSN Ref: P2023-0185-FSN

FSCA Ref: P2023-0185-FSCA

Date: 2023-04-17

Field Safety Notice
Impella 5.5 with SmartAssist heart pump

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
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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. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. 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.	5. Device Model/Catalogue/part number(s)*
	0550-0007; distributed as pump set with model number 0550-0002
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	A hospital specific list of affected products is provided in the attachment
1.	8. Associated devices
	N/A

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

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	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. 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 was assessed a reportable incident.
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

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	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 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. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required.	

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3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer***	
	☒ Product Removal ☐ Software upgrade ☐ Other ☐ On-site device modification/inspection ☐ IFU or labelling change ☐ 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).	
3.	6. 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 June 02 and July 28.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

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4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc.	
4.	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Serial number listing
4.	10. 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.

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	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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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Business Reply Form

Response is required

Recall Coordinator
<Customer Address>

By Signing this form, I am confirming that I have read and understand the recall (removal) instructions provided in this letter dated <*date*>

☐ Yes

Indicate disposition of product subject to this recall (removal) by marking the appropriate check box, filling out the Subject Product Information Table, and signing the acknowledgement signature section:

☐ Subject Unit(s) Have already been returned (Specify date(s) for appropriate serial number(s) in table below)

AND/OR

☐ Subject Unit(s) have been held for return (Indicate which serial number(s) below)

AND/OR

☐ Subject Unit(s) Have Been Used (Specify date(s) for appropriate serial number(s) in table below)

Subject Product Information Table		
Impella 5.5 with Smart Assist Model Number:		
Serial Number(s)	**Disposition** *(as indicated above)*	**Date of Return/Use** *(if applicable)*
<SN listing>		

Acknowledgement Signature		**Date**	
Print Name		**Telephone**	
Email			
Comment			

Please scan and email completed response to
sthoutam@abiomed.com
kwallbrueck@abiomed.com
meisen@abiomed.com.