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FSN Ref: 2023-FSN-00156 / 2023-FSN-00157 FSCA Ref: 2023-FA-00156 / 2023-FA-00157

Date: 2024-03-05

Field Safety Notice

Prevention of ventricular perforation and fiber ingestion for Impella heart pumps

For Attention of*: All Impella heart pump users involved in preparation and insertion of Impella heart pumps.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Oliver Goss; Abiomed UK Ltd., 1 The Green, Richmond, Surrey, United Kingdom, TW9 1PL; telephone +447957441827, email ogoss@abiomed.com

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Field Safety Notice (FSN)

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	All Models of the Impella CP heart pumps.
1.	2. Commercial name(s)*
	Impella CP SmartAssist; Impella CP
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Impella heart pumps are temporary intravascular micro axial blood pumps that supports a patient's circulatory system. The left-sided Impella catheters are inserted femorally or via surgical cut down through the axillary artery and into the left ventricle. When properly positioned, the Impella catheters deliver blood from the inlet area, which sits inside the left ventricle, through the cannula, to the outlet opening in the ascending aorta. The right-sided Impella catheter is inserted femorally into the right or left femoral vein. When properly positioned, the Impella catheters deliver blood from the inlet area, which sits inside the Vena Cava Inferior, through the cannula, to the outlet opening in the pulmonary artery.
1.	5. Device Model/Catalogue/part number(s)*
	0048-0014; 0048-0002.
1.	6. Software version
	Not relevant
1.	7. Affected serial or lot number range
	Not relevant
1.	8. Associated devices
	All Impella CP heart pump models are distributed in pump sets; besides the heart pump every pump set includes introducer(s), guidewire, purge cassette. The Impella CP pump set also includes a separate pump connector cable. All pump models are run by the Automated Impella Controller (AIC). The user monitors the pump through the AIC user interface.

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	During an internal review, Abiomed discovered that information on safe use of Impella pumps were issued with two technical bulletins (a.k.a. Impella Product Update), but the product(s) IFU were not updated to include the same level of detail covered in the bulletins and one of the bulletins was not distributed to European customers. This includes: 1) Technical bulletin for operator mishandling of the Impella left-sided devices resulting in

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	iatrogenic ventricular wall perforation. 2) Impella Product Update for an issue with fibers entrapped in the impeller.
2.	2. Hazard giving rise to the FSCA*
	Abiomed is issuing this FSCA to remind users of the Impella Updates, and subsequently update all IFUs with the corresponding information for routine distribution to users. Myocardial wall and vessel perforation associated with diagnostic or therapeutic procedures are common. Pericardial tamponade may rapidly evolve as a life-threatening complication, which requires immediate diagnosis and treatment. Ingestion of material into an Impella Heart Pump can result in low pump flow, high purge pressure, clot formation along the internal blood flow path, and the secondary failure of pump stop leading to loss of therapy. Most patients will require a pump exchange; in critical patients, failure of support can lead to further deterioration and worsening of life-threatening situation. Changes in the flow dynamic though the pump may result in increased hemolysis and the need for medical intervention.
2.	3. Probability of problem arising
	1) The complaint rate for ventricular perforation for Impella CP / Impella CP SmartAssist between September 2021 and April 2023 was 0.04%. (2) The rate of complaints for lower than expected pump flow, where the analyses showed that clots were formed around a matrix comprised of blue or white fibers typically found in sterile towels and drapes was consistently <0.02% (N=0-3 per year) for the past 10 years.
2.	4. Predicted risk to patient/users
	Severity of ventricular perforation is ‘critical’, as the event can directly or indirectly result in death. Based on the reports received for cardiac perforation since January 2018, the estimated likelihood of harm occurring is ‘unlikely’. Severity of fiber ingestion is ‘moderate’ for most patients when requiring pump exchange; severity can be ‘critical’ in some patients, where failure of support can lead to further deterioration and worsening of life-threatening situation. Based on historic rates (2013 and before) the likelihood of harm occurring is ‘likely’ for pump exchange, and ‘possible’ for failure to support. This also considers that it is common practice to rinse invasive devices before the procedure, to wipe catheter like devices with gauze and to control bleeding trough introducers using contact with a gauze or surgical towel.
2.	5. Further information to help characterise the problem
	There has been no recent observation of changes in trends or severity; rates remain stable over the past several years.
2.	6. Background on Issue
	During an internal review, Abiomed discovered that information on safe use of Impella pumps were issued with two technical bulletins (a.k.a. Impella Product Update), but the product(s) IFUs were not updated to include the same level of detail covered in the bulletins, and one of the bulletins was not distributed in Europe. The two technical bulletins are: (1) Recommendation to Avoid Synthetic or Cotton Fiber Contact with Impella Heart Pump. (2) Recommendations for avoiding Iatrogenic LV Perforation with the Impella Heart Pumps.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

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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 ☐ None **1: To reduce the risk of cardiac injury (including ventricular perforation), physicians should exercise special care when inserting the Impella Catheter in patients with complex anatomy. This includes patients with known or suspected decreased ventricular cavity size, ventricular aneurysms, congenital heart disease, or compromised cardiac tissue quality in the settings of acute infarction with tissue necrosis.** **2: To reduce the risk of vascular injury, physicians should exercise caution when inserting the Impella Catheter in patients with complex peripheral vascular anatomy. This includes patients with known or suspected: unrepaired abdominal aortic aneurysm, significant descending thoracic aortic aneurysm, dissection of the ascending/ transverse/descending aorta, chronic anatomical changes in the relationship of the aorta/aortic valve/ventricular alignment, significant mobile atheromatous disease in the thoracic or abdominal aorta or peripheral vessels.** **3: Physicians should exercise special care when inserting the Impella Catheter during active Cardiopulmonary Resuscitation (CPR). In addition, active CPR manoeuvrers may change the position of the Impella Device, introducing a risk of cardiac or vascular injury (including ventricular perforation). Check that the pump is positioned correctly in the left ventricle after CPR with echocardiography guidance.** **4: To reduce the risk of cardiac or vascular injury (including perforation) when manipulating the heart during cardiac surgery, evaluate the position of the pump using imaging guidance prior to manipulating the heart, and monitor position.** **5: To reduce the risk of cardiac or vascular injury (including ventricular perforation) when advancing or torquing the Impella, adjustments should be performed under imaging guidance.** **6: To reduce the possibility of fibers being drawn into the Impella, customers should avoid exposing the inlet and cannula section of the Impella Heart Pumps**

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	to any surfaces or fluid baths where the device can come into contact with loose or floating fibers. **7: To avoid fibers drawn into the Impella:** *** Keep the Impella Heart Pump in the packaging tray until just before insertion.** *** Do not attempt to run the pump in a basin of saline prior to insertion.** *** Do not attempt to rinse and reinsert the device after initial insertion.** *** Hold the surgical towel or 4 x 4 gauze pad away from the inflow and outflow windows, when controlling blood splatter during insertion of the Impella Heart Pump through the introducer.** **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?	Reinforcement of proper handling should be distributed to all Impella pump users 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 ☐ Software upgrade ☐ Other ☐ On-site device modification/inspection ☒ IFU or labelling change ☐ None Additional warnings and cautions will be added to IFU for Impella heart pumps.	
3.	5. By when should the action be completed?	Updated IFU will likely start distributing in May 2024.
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	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:	None
4.	10. Name/Signature	Karsten Wallbrück PRRC (EU MDR art. 15 (3) b)-e))

	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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Field Safety Notice (FSN)
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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2023-FSN-00156 / 2023-FSN-00157
FSN Date*	2024-03-06
Product/ Device name*	Impella heart pumps
Product Code(s)	0048-0014; 0048-0002

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
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.	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	EUFSCA@abiomed.com
Customer Helpline	+800 0 22 466 33
Postal Address	Abiomed Europe GmbH Att. of Karsten Wallbrück 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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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.