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FSN Ref: 2024-FSN-00019

FSCA Ref: 2024-FA-00019

Date: 2024-07-31

URGENT Field Safety Notice

Risk of optical sensor damage in Impella products when used concurrently and in close proximity with Shockwave Coronary IVL Catheter

For Attention of*: All Impella pumps with SmartAssist (left side) - Impella CP and Impella 5.5

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	All Impella pumps with SmartAssist (left side): Impella 5.5 SmartAssist and Impella CP SmartAssist
1.	2. Commercial name(s)*
	Impella 5.5 SmartAssist; Impella CP SmartAssist.
1.	3. Primary clinical purpose of device(s)*
	An Impella heart pump is temporary intravascular micro axial blood pump 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 Impella CP with Smart-Assist heart pump is intended for clinical use of up to 5 days, the Impella 5.5. with SmartAssist for up to 29 days.
1.	4. Device Model/Catalogue/part number(s)*
	0550-0002; 1000482; 0048-0014.
1.	5. Software version
	Not relevant
1.	6. Affected serial or lot number range
	Not relevant
1.	7. Associated devices
	All Impella heart pump models are distributed in pump sets; besides the heart pump every pump set includes introducer(s), guidewire, purge cassette and further pump model specific accessories for correct placement and running the pump. 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*
	Abiomed has determined that there is a risk of optical sensor damage in Impella products as listed above when used concurrently and in close proximity with Shockwave Coronary IVL Catheter which is in active distribution within your country or territory. Placement Signal Not Reliable alarm may occur and subsequently disable pump position monitoring. Loss of the placement signal does not impact Impella hemodynamic support.

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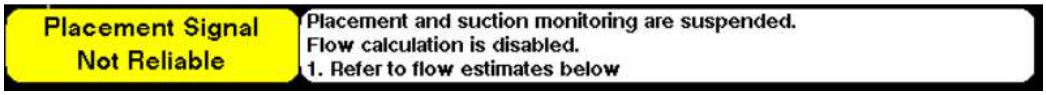
Example of a “Placement Signal Not Reliable” alarm that may occur:



No product design or manufacturing issues are related to this potential interaction, and hemodynamic support will not be affected as a result of optical sensor damage. Abiomed will modify the IFUs for the Impella products listed in Section 1.2 to inform users of this risk.

A complaint review from January 1, 2021 through June 14, 2024 has identified optical sensor damage in 0.43% of cases during Shockwave Coronary IVL Catheter use. No adverse events have been reported due to this interaction at this time.

Your local Health Authority has informed about IFU modifications described in Section 3 of this letter. The modifications include additions to Cautions section and to Patient Management Topics.

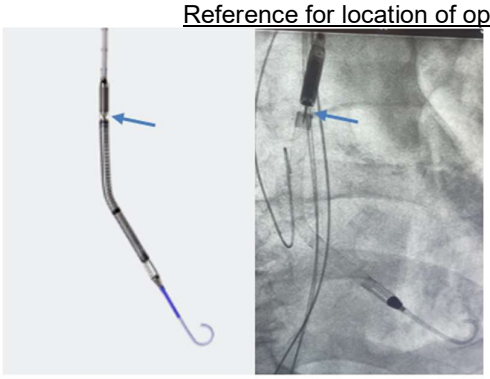
RECOMMENDATIONS:

Product in hospital inventory may continue to be used.

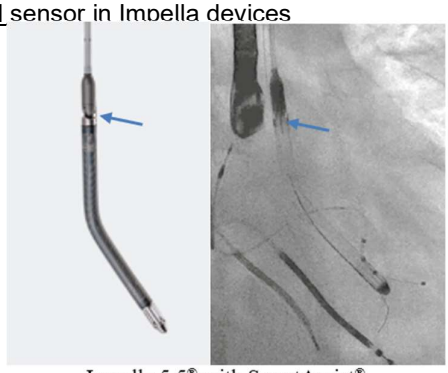
Abiomed recommends the user to maintain adequate distance (> 20 mm) between the IVL device and Impella optical sensor and include optimal positioning of the Impella catheter with the radiopaque marker band located at the aortic valve annulus.

If optical sensor failure occurs, monitor patient hemodynamics and confirm Impella positioning with imaging. The pump will still operate but placement and suction monitoring will be suspended.

Reference for location of optical sensor in Impella devices



Impella CP® with SmartAssist®



Impella 5.5® with SmartAssist®

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Product is NOT being removed from the field and does not need to be returned.
- Review, complete all fields, sign, and return the attached business response form (BRF) (refer to Attachment 2) to the Recall Coordinator identified in this document.
- 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

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	facility and provide them with this notice. • Post a copy of this notice in a visible area for awareness of this field safety notice. • As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported according to your procedures and applicable regulatory requirements. 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 your local clinical field staff. Thank you for your cooperation.
2.	2. Hazard giving rise to the FSCA*
	In the cath lab setting, where other imaging modalities and close clinical monitoring are readily available, the Impella device is usually removed at the conclusion of the elective PCI procedure; approximate Impact beyond users: No impact beyond the user- Impact from product removal: No product removal is considered, therapy is continued as planned. Therefore, a loss of the placement sensor is usually tolerated with minimal impact beyond a user inconvenience (S1). Patients with cardiogenic shock are expected to be less physiologically tolerant to delay or interruption of hemodynamic support. The potential for harm may sometimes arise when the physician chooses to replace the Impella device, as pump replacement is associated with an additional clinical intervention (S3). Pump replacement increases the potential risks associated with pump re-insertion and re-positioning. The clinician may also choose to keep the pump in situ despite the loss of the placement signal, relying on clinical evaluation and advanced imaging such as fluoroscopy and echocardiography to ensure correct pump positioning. It is crucial to note that if a sudden loss of pressure signal is observed on the Impella console, the Impella pump hemodynamic support will continue, but the positioning algorithms will no longer be operational.
2.	3. Probability of problem arising
	A complaint review from January 1, 2021 through June 14, 2024 has identified optical sensor damage in 0.43% of cases during Shockwave Coronary IVL Catheter use. No adverse events have been reported due to this interaction at this time.
2.	4. Predicted risk to patient/users
	Impact beyond users: No impact beyond the user- Impact from product removal: No product removal is mandated. There are no similar devices available.
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
	A higher rate of complaints was identified for pump optical sensor failure when interacting with known Shockwave presence. Without Shockwave interactions, the Impella CP damaged sensor complaint rate is 0.01% compared to the current complaint rate (0.41%) of Shockwave interactions normalized with Shockwave usages according to data from general usage reporting.
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 ☐ None **New Caution (Impella CP with SmartAssist, Impella 5.5 with SmartAssist):** • Use with Shockwave Coronary Intravascular Lithotripsy (IVL) Catheter at a distance of less than 20 mm between the optical sensor and IVL device may interfere with or damage the Impella optical sensor. Prior to IVL therapy pulsing, physicians should assess and verify this distance. If the placement signal is not displayed, monitor patient hemodynamics and confirm Impella position with imaging and motor current pulsatility. Loss of the placement signal does not impact Impella hemodynamic support. **Addition to Patient Management Topics (Automated Impella Controller with SmartAssist, Impella 5.5 with SmartAssist):** • Shockwave Coronary Intravascular Lithotripsy (IVL) Catheter. The pressure waves emitted from a Shockwave Coronary Intravascular Lithotripsy (IVL) Catheter may interfere with or damage the optical pressure sensor when the Shockwave Coronary IVL device is less than 20 mm from the Impella optical sensor. Best practices to maintain adequate distance between the Shockwave Coronary IVL device and Impella optical sensor include optimal positioning of the Impella catheter with the radiopaque marker band located at the aortic valve annulus. Prior to pulsing, physician users should ensure the shortest distance from the Shockwave Coronary IVL device to the Impella optical sensor is ≥ 20 mm. If the placement signal is not displayed, monitor patient hemodynamics and confirm Impella position with imaging and motor current pulsatility. Placement Signal Not Reliable alarm may occur and subsequently disable position monitoring. Loss of the placement signal does not impact Impella hemodynamic support. **To increase awareness of these recommendations:** *** Keep the copy of this FSN together with your IFU.**

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3.	2. By when should the action be completed?	Reinforcement of proper handling should be distributed to All Impella pumps with SmartAssist (left side) 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 ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ 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 March 2025.
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	Insert Name and Title here and signature below.

	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

1. Field Safety Notice (FSN) information	
FSN Reference number*	2024-FA-00019
FSN Date*	2024-07-30
Product/ Device name*	Impella 5.5 with SmartAssist and Impella CP with SmartAssist
Product Code(s)	0550-0002; 1000482; 0048-0014.

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.	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 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**

Mandatory fields are marked with *

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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.