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

# Field Safety Notice

## Prevention of ventricular perforation and fiber ingestion for Impella heart pumps

**Products Impacted:**
**All Impella heart pumps (including Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella RP)**

DATE: February 27, 2024

Dear DCH Auriga (Malaysia)

At Abiomed, Inc. ("Abiomed"), our first priority is to our patients, including the safe and effective use of our products.

Abiomed has initiated a **FIELD SAFETY CORRECTIVE ACTION (FSCA)** impacting all Impella pumps. During an internal review, Abiomed discovered that information on the safe use of Impella pumps was not incorporated into the product(s) IFU to inform customers of the potential risk of the inlet perforation through the myocardial wall of the left ventricle due to operator handling and the potential risk of fibers being drawn into the Impella, which may result in low flow of the device.

### PRIMARY CLINICAL PURPOSE OF DEVICE(S)

Impella heart pumps are temporary intravascular micro axial blood pumps that support 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.

### REASON FOR MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION (FSCA)

Abiomed is issuing this **FIELD SAFETY CORRECTIVE ACTION (FSCA)** to alert users of important Impella IFU Updates, and subsequently to 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,

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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.

## POTENTIAL PATIENT IMPACT:

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.

There has been no recent observation of changes in trends or severity; rates remain stable over the past several years.

## ACTIONS RELATED TO THIS FIELD SAFETY CORRECTIVE ACTION (FSCA)

**Abiomed requests that distributors take the actions below immediately to mitigate the risk.**

A. **Please notify HSA as soon as possible about this FSCA and confirm back to Abiomed.**

B. **Communicate the following additional warnings to customers. Ask the customers to complete and return the customer reply form (attachment 2) to you.**

C. **Ask all customers to maintain this field safety notification with the product IFUs to ensure continuing awareness of the FSN.**

D. **Complete and return the Business Reply Form Attachment 3**

## Additional Warnings:

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.

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3: Physicians should exercise special care when inserting the Impella Catheter during active Cardiopulmonary Resuscitation (CPR). In addition, active CPR maneuvers 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 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.

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN and respond with BRF. Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

Abiomed is updating IFUs with the new warnings as quickly as possible for inclusion with future devices.

Thank you for your cooperation.

Abiomed Inc.
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fieldaction@abiomed.com

**Attachments:**
Attachment 1 – Product Information Table
Attachment 2 –Field Safety Notice (FSN) and Customer Reply Form
Attachment 3 – Business Reply Form (BRF)

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# Field Safety Notice (FSN)

## Prevention of ventricular perforation and fiber ingestion for Impella heart pumps

### Attachment 1—Device Information

| Product/ Device name* | Impella heart pumps |
|---|---|
| 0048-0014 | Impella CP Set with SmartAssist |

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# Field Safety Notice (FSN)

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### Attachment 2—Field Safety Notice (FSN)

This notice needs to be passed on all those who need to be aware within your organization and/or to any organization where Impella pumps have been transferred.

Please transfer this notice to other organizations 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.*

# Field Safety Notice (FSN)

## Prevention of ventricular perforation and fiber ingestion for Impella heart pumps

## Customer Reply Form

| **1. Field Safety Notice (FSN) information** | |
|---|---|
| FSN Reference number* | 2023-FSN-000156 / 2023-FSN-000157 |
| FSN Date* | 2024-02-16 |
| Product/ Device name* | All Impella heart pumps |
| Product Code(s) | Need confirmation from Reg Affairs |

| **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 |

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| | | |
|---|---|---|
| ☐ | 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 | |
| Customer Helpline | |
| Postal Address | |
| Web Portal | |
| Fax | |
| Deadline for returning the customer reply form* | |

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

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# Field Safety Notice (FSN)

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### Attachment 3 -- Business Reply Form (BRF)

### Response is Required

DCH Auriga

Please complete this Business Reply Form within 3 business days upon receipt of the notification and return it to fieldaction@abiomed.com.

Check the following box that applies:

☐ I have read and understand the notification, and we confirm that there is no impact in Malaysia.

☐ I have read and understand the notification, and we have taken the actions necessary to report to health authority and to communicate to all customers within Malaysia.

By Signing this form, I am confirming that I have read and understand the notification instructions provided in this letter.

| | | | |
|---|---|---|---|
| **Acknowledgement Signature** | | **Date** | |
| **Print Name** | | **Telephone** | |
| **Email** | | | |
| Comments: | | | |

Please scan and email completed response to RecallCoordinators@abiomed.com.