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

URGENT: MEDICAL DEVICE CORRECTION (NOTIFICATION)

Update to Instructions for Use

Dear Valued Customer,

Abiomed, Inc ("Abiomed") has initiated a device correction (notification) to inform you of updates that are being added to the Instructions for Use (IFU) for all Impella products in the table below.

Products Associated:

- Impella 2.5®
- Impella CP®
- Impella CP® with SmartAssist®
- Impella 5.0®
- Impella 5.5® with SmartAssist® - S1 Configuration
- Impella 5.5® with SmartAssist® - S2 Configuration
- Impella RP®
- Impella RP® with SmartAssist®
- Impella RP Flex™ with SmartAssist®
- Impella LD®

IFUs Being Updated:

1) 0042-9028: 2.5®, 5.0®, LD®, CP®
2) 0048-9007: CP® with SmartAssist®
3) 0550-9002: 5.5® with SmartAssist® - S1 Configuration
4) 10003049: 5.5® with SmartAssist® - S2 Configuration
5) 0046-9062: RP®
6) 0052-9013: RP® with SmartAssist®
7) 10003286: RP Flex™ with SmartAssist®

LV perforation has been reported in patients who were supported by the Impella system in a total of 129 patients (0.06% of cases) worldwide from 2018 to present. Of these complaints 129 were reportable MDRs due to the serious nature of the injuries. Of these cases, 49 peri-procedural deaths have been reported.

LV perforation has been associated with both technical implantation of the device, cardiac manipulation, as well as repositioning of the intra-cardiac devices. There have been no reported perforations related to device manufacturing or design. Abiomed's IFU warnings reflect these observations.

US FDA reviewed and approved the IFU modifications, included in Attachment 1 in this letter. The modifications include: removal of Emergency Use Authorization section (Covid19), contraindications, potential adverse events, warnings, and cautions.

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) provided to

impacted customers and send it to Abiomed4112@sedgwick.com.

- 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 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 to the FDA's MedWatch Adverse Event Reporting Program using the link below: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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 recallcoordinators@abiomed.com and/or your local clinical field staff. Thank you for your cooperation.

Attachments: Attachment 1 – IFUs Modification Details

Attachment 1 – IFUs Modification Details

Potential Adverse Events (2.5, 5.0, LD, CP, CP with SmartAssist, 5.5 with SmartAssist [S1, S2]):
Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and ~~Vascular injury.~~ cardiac or vascular injury (including ventricular perforation).

Potential Adverse Events (Impella RP, RP with SmartAssist, RP Flex with SmartAssist):
Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device Malfunction, Hemolysis, Hepatic failure, Insertion site infection, ~~Perforation~~, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system complication, Tricuspid valve injury, ~~Vascular injury~~ cardiac or vascular injury (including ventricular perforation), Venous thrombosis, Ventricular fibrillation and/or tachycardia.

New Warning (All Products):

- **New Warning:** 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.

Additional relevant sections within IFU body include:

To avoid fibers drawn into the Impella.
* Keep the Impella Heart Pump in its 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.

New Warnings (2.5, 5.0, LD, CP, CP with SmartAssist, 5.5 with SmartAssist [S1, S2]):

- **New Warning:** 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.

- **New Warning:** 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.

  Addition for 5.0, 5.5 Only: In instances where the Impella pump has been placed prior to performing cardiac surgery with aortic cross clamping and cardioplegic arrest, care should be taken when manipulating the heart when the pump position is fixed with application of the aortic cross clamp across the pump catheter.

Redlined Cautions Moved to Warnings (2.5, 5.0, LD, CP, CP with SmartAssist, 5.5 with SmartAssist [S1, S2]):

- **Existing Caution:** Physicians should exercise special care when inserting the Impella Catheter in patients with known or suspected unrepaired abdominal aortic aneurysm or significant descending thoracic aortic aneurysm or dissection of the ascending, transverse, or descending aorta.
  - **New Warning:** 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.
  - **New Warning:** 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.

- **Existing Caution:** 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. Check that the pump is positioned correctly in the left ventricle after CPR with echocardiography guidance.
    - **New Warning:** 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 the risk of cardiac or vascular injury (including ventricular perforation). Check that the pump is positioned correctly after CPR with echocardiography guidance.

New Warnings (Impella RP, RP with SmartAssist, RP Flex with SmartAssist):

- **New Warning:** 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.
- **New Warning:** To reduce the risk of cardiac or vascular 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, thin-walled ventricles due to chronic dilation, congenital heart disease, or compromised cardiac tissue quality.

Redlined Warning (Impella RP, RP with SmartAssist, RP Flex with SmartAssist):

- **Existing Warning:** Torquing the catheter should be monitored carefully using fluoroscopy.
    - **Revised Warning:** 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.

Redlined Caution Moved to Warning (Impella RP, RP with SmartAssist, RP Flex with SmartAssist):

- **Existing Caution:** Physicians should exercise special care when inserting the Impella Catheter during Cardiopulmonary Resuscitation (CPR). In addition, active CPR maneuvers may change the position of the Impella device. Check that the pump is positioned correctly in the right ventricle after CPR with echocardiography guidance.
    - **New Warning:** 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 the risk of cardiac or vascular injury (including ventricular perforation). Check that the pump is positioned correctly after CPR with chest x-ray guidance.