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

<FIRST/SECOND/THIRD ATTEMPT>

URGENT MEDICAL DEVICE RECALL (REMOVAL)

Impella 5.5 with SmartAssist Set, US

Product Code: 0550-0008;

GTIN: 00813502011531

DATE: <date>

Recall Coordinator
<Customer Address>

Dear Valued Customer,

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

Abiomed is issuing a medical device recall (removal) of a subset of Impella 5.5 with SmartAssist Sets, Product Code 0550-0008 only. The subject devices are identifiable by a white label on the box, as described in Attachment 1 to this letter. Our records show that your facility received one or more units of the devices subject to this recall. Please carefully review this notice for the steps that you should take to respond to this medical device recall (removal). The Impella 5.5 with SmartAssist Sets with the preinstalled Sidearm Retainer and the new yellow luer are not part of this recall (removal).

INTENDED USE

The Impella 5.5® with SmartAssist® System is a temporary ventricular support device intended for short term (14 days) use and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

REASON FOR MEDICAL DEVICE RECALL (REMOVAL)

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 sodium bicarbonate 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.

POTENTIAL PATIENT IMPACT:

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 eventually, pump stop leading to loss of therapy. In critical patients with need for full support, failure of support can lead to further deterioration and worsening of critical situation.

ACTIONS RELATED TO THIS RECALL (REMOVAL)

Abiomed will replace all affected pumps that are still in your inventory using a phased replacement approach. The benefits of using the pump outweigh the risks of pump stop due to purge leaks. To mitigate leaks from sidearm damage and/or the yellow luer, it is critical to refer to the Important Information section below for best practices in the event you must use an affected Impella 5.5 with SmartAssist Set while you wait for a replacement pump. Please contact your Abiomed representative to receive a Sidearm Retainer and/or a Codan Extension Tubing Set if you do not have one. See Attachment 1 to this letter for your specific replacement date.

IMPORTANT INFORMATION

Since the implementation of the preinstalled sidearm retainer and the new yellow luer, the complaint rate for purge leak due to sidearm damage leading to a pump stop decreased to 0.22%. However, device units without these modifications are still in the field. Please follow these recommendations to 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) (e.g., ChloraPrep, Hibiclens, IPA wipes, IPA caps, Stryker Sage 2% Chlorhexidine Gluconate, 3M Duraprep) should never be applied to the Impella sidearm and purge filter.
- A Codan Extension Tubing Set should be used to support delivery of sodium bicarbonate purge solution. For maximum effectiveness, the extension tubing set should be installed dry to the yellow Luer on the Impella 5.5 purge sidearm at the beginning of the case and should not be disconnected or replaced for the duration of the case.
- Purge cassette changes can be performed less frequently (purge cassettes have been tested with bicarbonate for 5 days).
- Importance of three-point fixation of the sidearm as per the IFU.

Healthcare Providers should refer to Section 8 in the Instructions for Use (IFU) that describes the alarms for the purge system events and the High Motor Current events, and the communications Abiomed

previously issued specifically addressing these issues, including without limitation:

- Technical Bulletin: Reminder of Impella 5.5 with SmartAssist® Best Practices for Purge Management, April 2020 (available at: https://www.heartrecovery.com/resources/downloads/technical-bulletin-reminder-of-impella-55-with-smartassist-best-practices-for-purge-management); and
- Product Update: Heparin-Free Purge for All Impella Pumps, October 2022 (available at: https://www.heartrecovery.com/resources/downloads/product-update-heparin-free-purge).

You will find these communications enclosed.

Please contact Abiomed's Clinical Support Center, 1-800-422-8666, if you need any support troubleshooting a purge fluid leak or if you have any further questions.

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:

1. **Examine your inventory immediately to determine if you have product subject to this recall (removal). Refer to Attachment 1 for the Product Identification Tool to identify products that are subject to this Recall (Removal) by using package labels. DO NOT USE THE SUBJECT PRODUCTS UNLESS NO OTHER PRODUCT IS AVAILABLE.**
2. Contact the Abiomed customer support center to coordinate the return of the subject products according to your scheduled date in Attachment 1.
3. Review the IMPORTANT INFORMATION section above for best practices in the event you must use these devices while you wait for a replacement.
4. Review, complete **all** fields, sign, and return the attached Business Response Form (BRF) on the last page of this letter to the Recall Coordinator identified in this document. **IMPORTANT: Please complete the attached Business Response Form even if you have used any units of the subject product on hand.**
5. Forward this notice to any personnel in your facility who need to be informed.
6. If any of the product subject to this recall (removal) has been forwarded to another facility, contact that facility and provide a copy of this notice to the relevant personnel.
7. Post a copy of this notice in a visible area for awareness of this field safety notice.
8. 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

If you have questions or concerns regarding this notice, please contact (Shashi Thoutam) directly at +1(734) 262-6255 and/or your local clinical field staff.

Thank you for your cooperation.

Respectfully,

Shashi Thoutam
Sr. Manager, Global Quality Systems
ABIOMED. Inc.

22 Cherry Hill Drive
Danvers, MA 01923
Tel: +1 (734) 262-6255
sthoutam@abiomed.com

Attachments: Business Reply Form
Attachment 1 – Product Identification and Replenishment Tool

URGENT MEDICAL DEVICE RECALL (REMOVAL)

Impella 5.5 with SmartAssist Set, US

Business Reply Form (BRF)

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)/batch number(s) in table below)

AND/OR

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

AND/OR

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

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

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

Please scan and email completed response to sthoutam@abiomed.com or mail to the following address:

Shashi Thoutam (Sr. Manager, Global Quality Systems)
ABIOMED, Inc.
22 Cherry Hill Drive
Danvers MA, 01923

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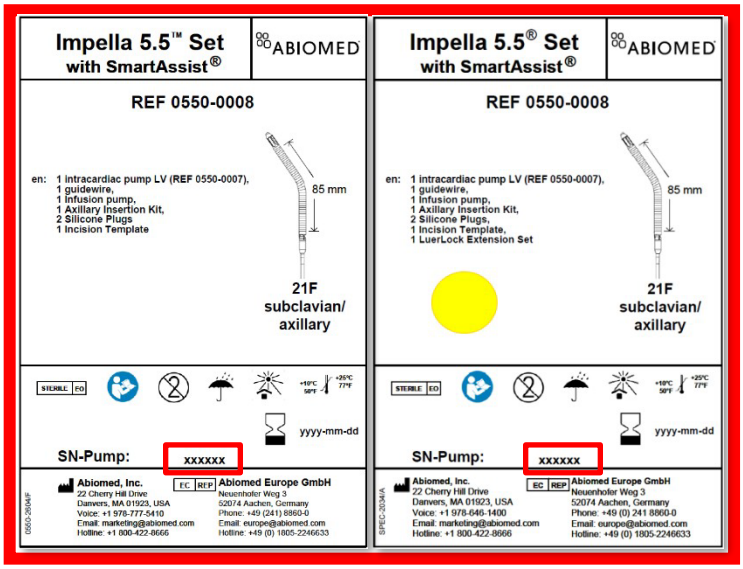
ATTACHMENT 1

Account Name: <Customer Details>

According to our records, the following subject unit was sold to you:

Batch Number	Serial Number	UDI

The **subject devices** have a white label on the outer box as highlighted in **red** below. You will find the serial number indicated in the small red box. Devices not subject to this recall have yellow and blue labels on the outer box, as highlighted in green below.



The anticipated date to receive replacement for your units is <Date Range>.

If you have questions or concerns, please contact customer service at (800) 422-8666 option 2 or email customerservice@abiomed.com and/or your local clinical field staff.