Johnson&Johnson MedTech

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FIRST ATTEMPT

URGENT MEDICAL DEVICE RECALL (REMOVAL)

Purge Cassette for Impella (*sold within Impella Pump Sets and Individually Packaged*)

Product Code	Product Description	Serial Number	UDI-DI
004334	Impella RP US Pump Set	434937A	00813502011029

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

February 18, 2026

Dear Valued Customer,

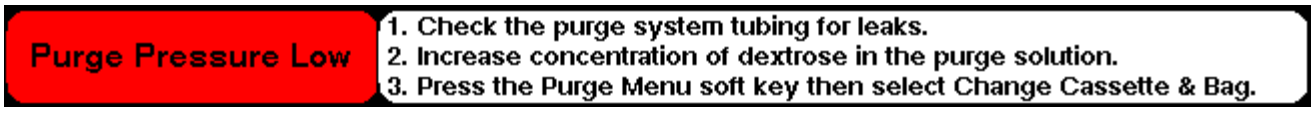
Abiomed, Inc. has issued a voluntary device recall (removal) of Purge Cassette (Generation 1) due to an increased risk of purge leaks. An updated Purge Cassette (Generation 2) is available with a lower risk of purge leaks. The purge cassette delivers rinsing fluid to the Impella catheter. The purge fluid flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor.

REASON FOR MEDICAL DEVICE RECALL (REMOVAL):

Abiomed implemented an updated design in the Purge Cassette (Generation 2) to reduce the risk of purge leaks by redesigning internal components. A review of global complaints from January 1, 2020, to December 31, 2025, found a Purge Cassette leakage rate of 0.31% in cases using Generation 1 and a lower rate of 0.02% in cases using Generation 2. This supports the effectiveness of this redesign and has led Abiomed to the decision to remove Generation 1 Purge Cassettes in markets where Generation 2 Purge Cassettes are available.

POTENTIAL PATIENT IMPACT:

If a Purge Cassette leak were to occur, the user would see a “Purge Pressure Low” alarm on the AIC; see example of alarm below:



A purge leak may lead to low purge pressure if it goes unaddressed. This can lead to biomaterial ingress, which may lead to a pump stop. A pump stop may result in a loss of hemodynamic support and lead to an outcome of death.

A review of global complaints from January 1, 2020, to December 31, 2025, found Purge Cassette leakage in 0.31% of cases using Generation 1 and 0.02% of cases using Generation 2. The complaints review determined that for cases using Generation 1, there have been no patient deaths attributed to this issue; however, in four (4) cases, the failure resulted in a pump stop and / or in the user choosing to exchange the pump or consoles, which is considered medical intervention. The complaints review also determined there have been no patient deaths or serious injuries attributed to this issue for cases using Generation 2.

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ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Review all Purge Cassettes within inventory and if any Purge Cassettes are identified as impacted per Attachment 1 - Instructions to Locate Purge Cassette (within Impella RP US Pump Set), please set aside and quarantine.
- A return shipment label has been provided to the impacted customer along with this letter. If impacted product is identified, utilize the return shipment label to initiate the return. If there are any questions on the return process and / or the need for new or additional labels, reach out to Sedgwick at Abiomed6349@sedgwick.com.
- Review, complete all fields, sign, and return the provided business reply form (BRF) (refer to Attachment 2) to Abiomed6349@sedgwick.com.
- Upon receipt of returned product and completed BRF by Sedgwick, Abiomed will provide a copy of a credit memo for the amount returned.
- Follow your standard process to order Generation 2 Purge Cassettes.
    - Use of a Purge Cassette is always required when using an Impella Pump. In the event that a Generation 2 Purge Cassette is not available to you and the use of a Generation 1 Purge Cassette is absolutely necessary, you may continue to use it. However, ensure increased monitoring of the Purge System and refer to the IFU if a "Purge Pressure Low" alarm is triggered.
- 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.
- 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 as per below instructions:
    - Complete and submit the report online: www.fda.gov/medwatch/report.htm or
    - Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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 OneMD-Field-Actions@its.jnj.com or your local clinical field staff. Thank you for your cooperation.

Attachments:
Attachment 1 – Instructions to Locate Purge Cassette (within Impella RP US Pump Set)
Attachment 2 – Business Reply Form

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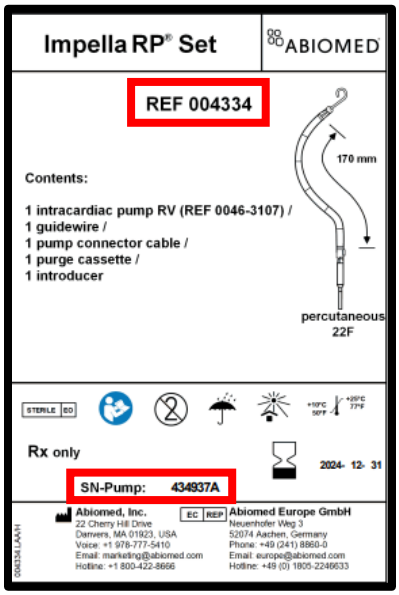
Attachment 1 – Instructions to Locate Purge Cassette (within Impella RP US Pump Set)

Instructions to identify impacted Purge Cassette within Impella RP US Pump Set:
It was identified that the impacted facility was shipped the below impacted Impella RP US Pump Set:

Product Code	Product Description	Serial Number	UDI-DI
004334	Impella RP US Pump Set	434937A	00813502011029

Locate the Pump Set reference number (004334) and serial number (434937A) printed on labeling as indicated below.



If the Purge Cassette was removed from the pump set, review your inventory to locate the reference number 0043-0001 or GTIN 00813502011999 on the label of the Purge Cassette pouch to identify the product subject to this recall.