Johnson&Johnson MedTech

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URGENT MEDICAL DEVICE RECALL (REMOVAL)

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

Product Code	Product Description	Affected Lot
0043-0001	Purge Cassette, Sterile	All unexpired Generation 1 Purge Cassette(s)
0043-0002	Purge Cassette, Packaged	
0043-0003	Purge Cassette, 5 Pack	
0043-0009	Purge Cassette, Sterile	
0043-0014	Purge Cassette, Sterile	
0048-0014	Impella CP Smart Assist Set	
004413	Impella 2.5 Set	
0046-0011	Impella RP Pump Set, EU	
005060	Impella 5.0 IMC Pump Set	
1000362	5.5 Accessories AU	

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

March 3, 2026

Dear Valued Customer,

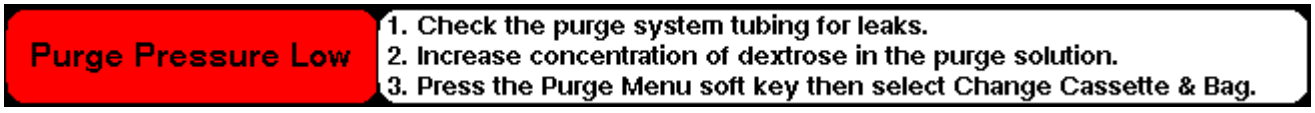
Abiomed, Inc. has issued a voluntary device recall (removal) of Purge Cassette (Generation 1) due to an increased risk of purge leaks. An updated Purge Cassette (Generation 2) has been developed with a lower risk of purge leaks. The purge cassette delivers rinsing fluid to the Impella catheter. The purge 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. Abiomed has made 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.

We are coordinating the product removal and replacement process and will contact you with next steps. In the meantime, you may continue using the Generation 1 Purge Cassette until Generation 2 Purge Cassette stock becomes available. However, please ensure increased monitoring of the Purge System and refer to the IFU if a "Purge Pressure Low" alarm is triggered. Use of a Purge Cassette is always required when using an Impella Pump. The overall benefit of the Impella system continues to outweigh the risk associated with Generation 1 Purge Cassette leaks.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Review, complete all fields, sign, and return the attached business reply form (BRF) (refer to Attachment 1) to your local Abiomed representative.
- 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 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 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.

Attachments:
Attachment 1 – Business Reply Form

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Attachment 1 – Business Reply Form (BRF)

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0046-0011	Impella RP Pump Set, EU	
005060	Impella 5.0 IMC Pump Set	
1000362	5.5 Accessories AU	

Please complete this Business Reply Form **within 3 business days upon receipt of the notification** and e-mail this form to your local Abiomed representative. If you have questions regarding returning this form, please contact your local Abiomed representative.

Acknowledgement Signature	kay	**Date**	4 March 2026
Print Name	Kamilatulhusna	**Telephone**	03-55438724
Account Name & Address	DCH Auriga (M) Sdn Bhd, Lot 6, Persiaran Perusahaan, Seksyen 23, 40300 Shah Alam, Selangor Darul Ehsan, Malaysia.		
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Comments:			