

Urgent Field Safety Notice

Regarding use-by-date mismatch for

Impella® Purge Cassette

Return to manufacturer

FSN Reference: HHE-2021-002

Aachen, June 16, 2021

Dear Valued Customer,

This letter is to notify you that Abiomed Inc. is recalling a small number of Impella Purge Cassette product.

Affected devices:

This information concerns the Impella® Purge Cassette, provided to you as boxes containing 5 sterile Purge Cassette devices (figure 1).



Figure 1: Sterile Purge Cassette



Description of the problem:

Abiomed has identified a situation in which a small percentage of product does not have the correct expiration date on the outer packaging label.

Hazard giving rise to this Field Safety Corrective Action:

The use of the device beyond the expiration date could result in infection due to a seal failure of the sterile barrier which may result in compromised sterility of the product.

The risk of patient harm is possible if an expired product is used.

Recommendations:

Any impacted product that is affected should be immediately removed from inventory and returned to Abiomed Europe GmbH for replacement.

The following affected units have been purchased by you:

Model Number	Batch Number
0043-0003	

Please return these products using the following return authorization number _____

Our Customer Service is going to contact you to discuss details of the product return. You will subsequently receive a replacement.

Please sign and return the attached recall return response letter via email or mail:

Scan and email completed response to kwallbrueck@abiomed.com

OR

Mail to:

Karsten Wallbrück
Abiomed Europe GmbH
Neuenhofer Weg 3
52047 Aachen
Germany

If you have questions or concerns regarding this notice, please contact us directly at any of the below listed numbers.



Pass on this information:

This **Field Safety Notice** needs to be passed on to all Impella heart pump users and those who need to be aware within your organization. In case you have passed Impella products to third parties, please make sure to forward this information to any organization where the potentially affected devices have been transferred.

This Field Safety Notice has been notified to the appropriate Competent Authorities and Regulatory Agencies.

Contact reference person:

For further questions please contact:

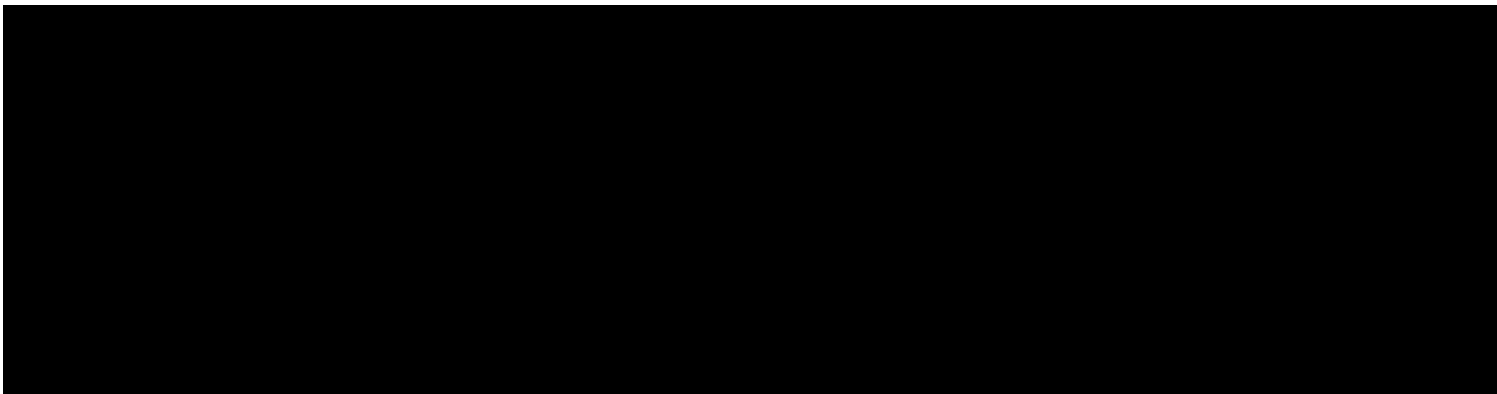
Max Eisen: +49 (0) 241 8860-226 meisen@abiomed.com

Karsten Wallbrück: +49 (0) 241 8860-114 kwallbrueck@abiomed.com

Thank you for your cooperation and we apologize for any inconvenience this may cause.

Respectfully

Abiomed Europe GmbH





**Medical Device Recall Returned Response
Acknowledgment and Receipt Form
Request is Required**

[Insert Hospital]

I have read and understand the recall instructions provided in the letter dated June 16, 2021.

_____ Yes

Indicate disposition of recalled product:

- Returned (Specify Quantity, date) or Held for Return
- Used (If yes, please provide the date and quantity)

Affected Product Information Table			
Model Number	Batch Number	Quantity in Inventory	Quantity Returned

Signature:

Print Name:

Date:

Telephone:

Email Address:

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

OR

Mail to:

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Abiomed Europe GmbH
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52047 Aachen
Germany