

Ablomed Europe GmbH • Neuenhofer Weg 3 • 52074 Aachen • Germany

[REDACTED]

Your Reference:  
N/A

Our Reference:  
[REDACTED]

Date:  
5. Jul 2010

**Urgent Safety Information - Impella® 5.0 – Device Recall**

Dear valued customer,

Ablomed recently received a customer complaint about an Impella® 5.0 that ruptured during explantation. This incident was preceded by continuous unresolved problems with high purge pressure after the pump was implanted in an axillary approach.

Our internal failure investigation has determined that the most likely root cause is an isolated failure in one production batch with the risk of a device rupture and subsequent loss of pump support or even loss of components. As we cannot exclude that this failure is also present in the rest of the production batch, we will preventively recall the rest of the batch.

Our internal documents show that you received the following products that are under suspicion. Therefore, we need you to complete and return the attached form.

Product	Material No.	Serial No.
Impella 5.0 Set	004840	45921
Impella 5.0 Set	004840	45922
Impella 5.0 Set	004840	45923
Impella 5.0 Set	004840	45924

If you still have the listed products on stock we ask you to separate them and will contact you immediately to arrange for return and compensation.

We regret the inconvenience this might cause and thank you for your understanding and support.

Yours sincerely,

[REDACTED]

Director QA Europe

**ABIOMED Europe GmbH**

Management Board:

Dr. Thorsten Sieß  
Dirk Michels

Commercial Register No.:

Amtsgericht Aachen HRB 13059  
VAT ID No.:  
DE 313 647 191

Bank Account:

Sparkasse Aachen BLZ 390 500 00, Kto.: 47 866 322  
IBAN: DL 153 905 000 000 47 866 322  
SWIFT/BIC: AACSD33

Contact Category

- 1<sup>st</sup> Contact
- 2<sup>nd</sup> Contact
- 3<sup>rd</sup> Contact

**Impella Pump Sets – Field Corrective Action**

Please fill this form out completely and email, return or fax to [REDACTED]:

ABIOMED Europe GmbH  
 ATTN: [REDACTED]  
 Neuenhofer Weg 3  
 52074 Aachen  
 FAX: +49 – (0) 241 – 8860 - 444  
 email: [REDACTED]@abiomed.com

Customer Name: [REDACTED]

Address: [REDACTED]

City / Zip: [REDACTED]

Ref# Impella Pump Set	Impella Serial Number	Used	In Inventory
004840	45921		
004840	45922		
004840	45923		
004840	45924		

**Acknowledgement**

- We acknowledge receipt of the Abiomed notification package dated 2010-07-05.

**Identification/Verification**

- We have reviewed our Impella inventory and verified that all areas where affected product could be located have been checked (e.g., Cath Lab, Central Supply, Receiving, other).
- We have contacted customers to which we have distributed affected products. (If applicable)

**Status of Affected Product**

- We do not have any affected product left on stock.
- We have found and separated affected product as indicated above.

Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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