

Urgent Security Information

**Recall for Medical Product**

regarding

Loglysis-Catheter for intravascular treatment  
REF 1725-2110 Batch no. 6000027363

Date 25 June 2009

**Sender:**

[REDACTED] Security Delegate for Medical Products, OptiMed GmbH, Ferdinand-Porsche-Strasse 11,  
76275 Ettlingen, e-mail: j.degener@opti-med.de

**Receiver:**

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**Identification of the affected medical product:**

Loglysis-catheter for intravascular treatment, 5F (1,67mm), 110cm, Lysis distance 10cm

Item number	Batch number
1725-2110	6000027363

**Problem definition inclusively determined cause**

OptiMed is hereby conducting a voluntary recall of one specific batch no. of OptiMed- products with the name "Loglysis-catheter for intravascular treatment". At this batch number the distal marker could loose from the tip of the catheter. As a result embolisms and thrombi could happen. The only products that are affected of this recall are from Batch no. 6000027363.

## What kind of actions have to be taken by the user?

Our records show that you have received loglysis-catheters from the affected batch number. On page 4 of this letter you find the Answer Letter that indicates which loglysis-catheters have been sent to you, including the Item Number and Batch number.

Please be aware that only the Products listed on the Answer Letter are affected by this voluntary recall.

Because of this situation we ask for your cooperation. To proceed correctly, please read the following instructions.

1. Remove from your inventory all affected Products and preserve in separate area. These products cannot come into clinical use.
2. Advise OptiMed in the Answer Letter how many from the affected Products will be sent back and how many have already been used.
3. Fill out and sign the Answer Letter, also when no units of the affected Product will be returned.
4. Send the completed Answer Letter by Fax, E-mail or Post to OptiMed as soon as possible.
5. Send only affected Products to the OptiMed address listed on the Answer Letter. For all sterile Products returned, a Credit Note will be issued.

We apologize for any inconvenience this has caused and thank you for your understanding.

## Transmission of the described information

Please assure in your organization that all users of the above mentioned products and other persons are informed about this **Urgent Security Information**. In case you have passed the products to third party, please forward a copy of this information or inform the below mentioned contact persons.

Please keep this information up to this action is finished.

The Federal Institute for Drugs and Medical Devices, Germany, got a copy of this "Urgent Security Information". Your National Competent Authority will be informed as well.

**Contact person**

For further questions to this recall, our Quality Management Department is available under the telephone number: +49 7243 7633 531, [j.degener@opti-med.de](mailto:j.degener@opti-med.de).

For further details to your return of affected products and the issue of a Credit Note, please contact our Customer Service: +49 7243 76 33 524.

Thank you in advance for your cooperation.

Best regards,  
**OptiMed GmbH**



Security Delegate for Medical Products  
Quality Management

PLEASE RESPOND as quickly as possible PER FAX to +49 7243/ 76 33 584

e-mail: [j.degener@opti-med.de](mailto:j.degener@opti-med.de)

Or by Post to: *OptiMed Medizinische Instrumente GmbH, Ferdinand-Porsche-Str. 11,  
D- 76275 Ettlingen, Germany*

***Urgent Answer:***

***Voluntary Recall of***

**Loglysis-catheter for intravascular treatment**

**REF 1725-2110 Batch no. 6000027363**

Customer: [REDACTED]

Past shipments of affected Product:

<i>Item number</i>	<i>Product name</i>	<i>Batch number</i>	<i>amount</i>	<i>already used</i>	<i>to be returned</i>
1725-2110	Loglysis-catheter for intravascular treatment	6000027363	5		

*Please add details about usage and as the case may be about return consignment of affected Products.*

*Please fill out for eventual questions:*

<i>Contact partner:</i>	
<i>Telephone Number:</i>	
<i>Date:</i>	
<i>Signature</i>	