optimed GmbH · Postfach 100665 · D-76260 Ettlingen

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Our reference	Telephone	Telefax	E-mail	Date
2016-01	[redacted]	07243/7633-99	vigilance@opti-med.de	20.04 2016

To: Risk Management Director or Material Management
(Please forward this letter to all potential users of the product e.g. vascular surgeons, interventional radiologists, neuro-radiologists or angiologists.)

Urgent Field Safety Notice – Voluntary Medical Device Recall
Zelos PTA-balloon catheter

Dear customer,

We would like to inform you that optimed Medizinische Instrumente GmbH initiates a voluntary recall of the Zelos PTA-balloon catheter.

The evaluation of tests additionally performed to our routine monitoring of the sterilization process has revealed that the sterility of Zelos PTA-balloon catheters cannot be assured prior to usage.

There is a risk that usage of non-sterile products may lead to inflammation or infection. Until today, April 20th 2016, optimed has not received any customer complaint or report on patient health impairment due to a lack in sterility.

To ensure optimal safety of our products we decided to perform a voluntary recall of all Zelos PTA-balloon catheters that have not yet exceeded the shelf life of 5 year.

The following reference numbers are affected by the recall:

Reference	Short description	Description

Reference number and lot number are printed on the label of the primary and secondary packaging.
Our records show that you have received some of the affected products. On page 4 of this letter (answer letter) you will find the information with the affected products that have been sent to you, including the reference and lot number as well as the delivered quantity.

Which actions have to be taken by the user?
Please be aware that only the products listed on the answer letter are affected by this voluntary recall. Please read the following instructions and carry out the described actions.

1. Please remove all affected products from your inventory, block and store them in a separate area. These products must not come into clinical use.

2. **Patients treated with a Zelos PTA-balloon catheter that is affected by this recall should be further monitored according to the clinical routine of the treating hospital.**

3. Please forward this letter to all staff members in your organization that need to be aware of this information letter and the initiated recall.

4. Please fill in the answer letter indicating the quantity of products that have already been used and the quantity of products that are being returned as well as your contact details.

5. Please return the completed and signed answer letter to optimed by fax, e-mail or mail **within 10 calendar days,** even if you are not going to return any product.

6. If you have additional questions regarding return of the products, credit note, replacement or shipping, please contact your optimed sales representative or our customer service at **+49 7243 76 33 524**.

7. Please only return affected products listed in the answer letter to optimed. A credit note will be issued for all sterile products returned.

8. In case you, as a distributor, have passed these products to third parties, please forward a copy of this information to each party and ensure that you receive back the information about products already used and products to be returned from your customers (e.g. hospitals).

   This information should be filled in the answer letter.

9. You are kindly requested to maintain awareness of this notice until all required actions within your organization have been completed.

10. Please make sure that your organisation and your customers are aware of the content of this information letter over an appropriate time period.

The return of this answer letter is crucial for optimed to complete this FSCA. Therefore, your cooperation in this matter is greatly appreciated.

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

Informing the authorities

European Union

Your Competent Authority was informed about this incident and has received a copy of this Field Safety Notice.

Countries outside European Union
Since you are acting as both, our distributor and our local representative, we kindly request you to inform your local authorities about this recall. In case of queries from the authority please forward this information to us via e-mail to vigilance@opti-med.de.

Thank you in advance for your cooperation.

Kind Regards

optimed GmbH

[redacted]

PLEASE RESPOND within 10 days

per fax to: +49 (0) 7243/ 76 33 99
e-mail: vigilance@opti-med.de
or by mail to: optimed Medizinische Instrumente GmbH
Ferdinand-Porsche-Str. 11
D- 76275 Ettlingen, Germany

URGENT FIELD SAFETY NOTICE

Voluntary **MEDICAL DEVICE RECALL**

Zelos PTA-balloon catheter

Customer:

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Delivered products:

Please fill out legibly the last two columns and complete your contact data in capital letters.

Reference number	Article description	Lot number	Delivered quantity	Used quantity	Quantity to be returned

Contact person:	
Phone number:	
Date:	
Signature:	

If you have additional questions regarding the return of the products, credit note, replacement or transport please contact your optimed sales representative or our customer service at
+49 7243 76 33 524 or service@opti-med.de.

Thank you in advance for your prompt response and your cooperation.