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Our reference	Telephone	Telefax	E-mail	Date
2016-01	07243/7633-0	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
Please see list of affected Lots at the end of this FSN		


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](mailto:vigilance@opti-med.de).

Thank you in advance for your cooperation.

Kind Regards

**optimed** GmbH

Dr. Benjamin Hundsdörfer  
Health and Safety Officer for Medical Devices

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:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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.

**Affected Lots - Recall 2016-01 optimed Zelos PTA-balloon catheter**

Reference no.	Lot	Description
1740-1604	6000074205	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-2004	6000074681	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 20 mm x 4 cm
1740-1602	6000078284	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 2 cm
1740-1404	6000085401	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1604	6000086404	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1404	6000087153	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1204	6000087410	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 4 cm
1740-1604	6000087606	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1402	6000088219	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 2 cm
1740-1202	6000088852	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 2 cm
1740-1204	6000088853	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 4 cm
1740-1404	6000089234	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1804	6000089235	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 18 mm x 4 cm
1740-1604	6000089287	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-2804	6000044455	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 28 mm x 4 cm
1740-1802	6000085154	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 18 mm x 2 cm
1740-1602	6000088854	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 2 cm
1740-1804	6000089235	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 18 mm x 4 cm
1740-1202	6000090154	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 2 cm
1740-1402	6000090402	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 2 cm
1740-1204	6000090640	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 4 cm
1740-2404	6000090642	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 24 mm x 4 cm
1740-1602	6000092531	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 2 cm
1740-1604	6000092633	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm

1740-1404	6000092752	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1604	6000093334	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1204	6000093499	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 4 cm
1740-1404	6000094409	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1802	6000095297	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 18 mm x 2 cm
1740-1804	6000095298	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 18 mm x 4 cm
1740-1202	6000095594	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 2 cm
1740-2604	6000095980	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 26 mm x 4 cm
1740-1204	6000098029	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 4 cm
1740-1404	6000098030	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1604	6000099464	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1204	6000099911	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 4 cm
1740-1404	6000100158	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1404	6000100539	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1204	6000101089	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 4 cm
1740-1604	6000101092	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1404	6000101133	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1404	6000102421	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1602	6000102422	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 2 cm
1740-1604	6000102752	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-2004	6000102753	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 20 mm x 4 cm
1740-1204	6000103113	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 12 mm x 4 cm
1740-1404	6000103303	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1404	6000103937	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1604	6000104686	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1404	6000105029	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-2804	6000106183	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 28 mm x 4 cm
1740-1604	6000108941	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm

1740-2004	6000109577	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 20 mm x 4 cm
1740-1602	6000112476	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 2 cm
1740-1604	6000112600	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1602	6000115934	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 2 cm
1740-1602	6000120181	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 2 cm
1740-1604	6000120862	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1604	6000121108	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1404	6000126155	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1604	6000126456	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1404	6000127282	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1604	6000128186	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1404	6000128648	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1404	6000129914	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1604	6000129916	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-2804	6000130515	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 28 mm x 4 cm
1740-1604	6000130956	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm
1740-1404	6000131502	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 14 mm x 4 cm
1740-1604	6000131824	Zelos PTA-Balloon Catheter Shaft-Length 100 cm Balloon 16 mm x 4 cm