optimed GmbH · Postfach 100665 · D-76260 Ettlingen

URGENT FIELD SAFETY NOTICE

Medical Device Recall (R2017-02)

Percutaneous Introducer Sheath 7F and 8F

Telephone	Telefax	e-mail	Date
07243 / 7633-0	07243 / 7633-99	vigilance@opti-med.de	30.06.2017

Dear customer,

optimed Medizinische Instrumente GmbH initiates a Medical Device Recall of the following products and lot numbers:

Type of corrective action:	Recall	
Reference optimed:	R2017-02	
Short description	**Reference**	**Lot**
Percutaneous Introducer Sheath 7F	1221-2410	6000085024 6000089219 6000089541 6000090045 6000091394 6000107052 6000109310 6000111473 6000112973 6000114693 6000127471 6000128705 6000133279 6000135451 6000139415 6000139896 6000142179 6000149797
Percutaneous Introducer Sheath 8F	1221-2510	6000090089 6000092583 6000093071 6000095967 6000096862 6000100566 6000107368 6000110213 6000110584 6000111598 6000111963 6000113136 6000114622 6000114949 6000116174 6000117321 6000119266 6000123352 6000126102 6000126776 6000126921 6000127727 6000129834

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Percutaneous Introducer Sheath 8F (*continued from page 1*)	1221-2510	6000130618 6000130787 6000133332 6000140251 6000141635 6000144061 6000146049 6000149652 6000150538 6000153224

Description of the facts:

The haemostatic valve of the percutaneous introducer sheath may exhibit an insufficient sealing performance.
Only the sizes 7F and 8F and listed lot numbers are affected. The percutaneous introducer sheath 6F has a different valve and is **not** affected by this recall.

Potential hazards:

Especially during arterial application the percutaneous introducer sheath may lead to an additional blood loss and may prolong the intervention.

Risk mitigation:

Affected products should not be used on the patient.

Corrective actions:

Blocking of all affected products and storage into a separate area.
These products may no longer come into clinical use.
Return of all products of the affected lots.

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Actions that have to be taken by the customer:

Please be aware that only products listed in the Field Safety Notice are affected by this recall. Please carefully 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. Please forward this Field Safety Notice to all staff members in your organization who need to be aware of this information and the initiated recall.

3. Please fill in the attached reply form **in full**.

4. Please return the **signed reply form** to optimed by e-mail **within 10 calendar days,** even if you are not going to return any products (vigilance@opti-med.de).

5. Please only return affected products listed in the Field Safety Notice to optimed. A credit note will be issued for all sterile products returned.

6. You are kindly requested to maintain awareness of this Field Safety Notice until all required actions within your organization have been completed.

7. In case you have passed these products to third parties, please forward a copy of the **Field Safety Notice** and the **reply form** to each party.

Additional actions that have to be taken by distributors:

8. Please ensure that you receive back all **completed and signed** reply forms from your customers (e.g. hospitals).

9. Please **summarize all statements** from your customers **in your reply form**.

10. In order to complete this Field Safety Corrective Action optimed GmbH needs a written confirmation that all your customers were successfully informed about this recall. **Please confirm this in your reply form**.

optimed has to document this recall. Therefore, the **return of the completed and signed reply form** is crucial to complete this Field Safety Corrective Action. Your cooperation in this matter is greatly appreciated.

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 90 54** or service@opti-med.de.

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Informing the authorities:

European Union (including Turkey and Switzerland)
Your National Competent Authority was informed about this recall 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.

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

Kind regards

optimed Medizinische Instrumente GmbH

Dr. Ernst Nennig
Safety Officer for Medical Devices

optimed GmbH · Postfach 100665 · D-76260 Ettlingen

Reply Form

Please respond **within 10 calendar days** by e-mail: **vigilance@opti-med.de**

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☐ We received the Field Safety Notice and implemented all required measures. We confirm that **all affected products in our inventory** were identified and **will be returned** (see table below).	☐ We received the Field Safety Notice and implemented all required measures. We confirm that we have **no more affected products in our inventory**.

If you have affected products in stock, please list the reference numbers, lot numbers and the quantity of each lot to be returned. Please expand the table if necessary. If you have no more affected products in stock you may leave the table blank.

Reference no.	**Lot no.**	**Quantity to be returned**
		Press <TAB> to add row

If you have 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 90 54** or service@opti-med.de.

Contact information / Confirmation

Please fill in (legibly) your data in block letters. Please **confirm both** that your statement is correct and that affected customers or users were notified. **Print** and **sign the reply form**.

Name:		**Client no.:**	
e-mail:		**Phone number:**	
Hospital / Company:			
Address:			
☐	We hereby confirm that the information provided in this form is correct and complete.		
☐	We hereby confirm that all affected customers or users were notified.		
Signature:		**Date:**	DD / MM / YY

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