optimed GmbH · Postfach 100665 · D-76260 Ettlingen

# URGENT FIELD SAFETY NOTICE
## Safety information (S2018-01)
## sinus-SuperFlex-635


| Telephone | Telefax | e-mail | Date |
|---|---|---|---|
| +49 7243 / 7633-0 | +49 7243 / 7633-99 | vigilance@opti-med.de | 18.01.2018 |


Dear customer,

optimed Medizinische Instrumente GmbH informs you about an important safety information.

| Type of corrective action: | Safety information | |
|---|---|---|
| Reference optimed: | S2018-01 | |
| **Short description** | **Reference** | **Lot** |
| Sinus-SuperFlex-635, Stent System vascular/biliary, 7mm x 80mm, Application Device 6F/75cm, .035i | 8607-6080 | Q024905 |

**Description of the facts and the root cause:**
The expiry date on the label on the outer packaging (card box) indicates inadvertently “2108-11”, the correct expiry date is: “2018-11”. The information on the label on the inner packaging (sterile packaging) is correct.

**Potential hazards:**
There are no risks for patient, user or third parties. The incorrect information for the expiry date on the outer packaging can only lead to uncertainty.

**Risk mitigation:**
n/a

**Corrective actions:**
The incorrect information on the affected products shall be corrected; the label shall be pasted over with a correct label by optimed or the responsible distributor. In addition, all customers who received affected products shall be informed by this Safety Information.

**Action to be taken by <u>distributor</u>:**

1. Check your stock for products of the affected lot number.
2. Additionally, check if products of the affected lot number were delivered to end users. If yes, forward this Safety Information and the reply form to the affected end users.
3. Please inform us with the attached reply form about the number of affected products which are present at your stock and your end user’s stock and which were not yet used. You will receive replacement labels to paste over the inaccurate labels. These replacement labels must be pasted onto the affected products after diligent identity verification of lot number and reference number only by you or your staff. The replacement labels must not be handed over to end users or third parties.
4. After this corrective action please fill in the second section of the reply form and send it to us to inform us about the number of corrected products.
5. Redundant replacement labels, which are not used, must be shredded, they must not be preserved.

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**Action to be taken by customers:**

Please carefully read the following instructions and carry out the described actions.

1. Please forward the Field Safety Notice to all staff members in your organization who need to be aware of this information.

2. Please ensure that this safety information is taken into consideration during clinical use.

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

4. Please return the **signed reply form** to your distributor (end users) or to optimed by e-mail (vigilance@opti-med.de, distributors) **within 10 calendar days**.

5. 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.

optimed has to document this safety information. Therefore, the **return of the 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 this safety information, please contact your optimed sales representative or our customer service at **+ 49 7243 76 33 90 54** or service@opti-med.de.

**Informing the authorities:**

**European Union (including Turkey and Switzerland)**
Your Competent Authority was informed about the Field Safety Notice 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 Field Safety Notice. 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
Health and Safety Officer for Medical Devices