Spiegelberg
Technology for brains

Spiegelberg GmbH & Co. KG · Tempowerkring 4 · 21079 Hamburg · Germany

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| Ref. Spiegelberg | Ref. BfArM |
|---|---|
| CMP-202407002 | Fall-Nr. 22766/24 |

Hamburg, 16.07.2024

# Urgent Information for Field Safety Corrective Action

## concerning:

**Spiegelberg Silverline® Ventricular Catheter 8F**
**AN: EVD30.010.02**
**LOT: 330 0 0137 24**

Dear valued Spiegelberg Customer,

As a precautionary measure, Spiegelberg GmbH & Co KG (subsequently: Spiegelberg) is providing, in the form of this notice, a customer information regarding a corrective action in the field for the Spiegelberg Silverline® Ventricular Catheter 8F. According to our documentation, you received one of the possibly affected catheters. With this notice we would kindly like to inform you about a possible security concern, that came to our attention.

## Details on affected devices

All complaints regarded the "**Silverline® Ventricular Catheter 8F**". Only the LOT 330 0 0137 24 is affected. The catheters are used for the drainage of cerebrospinal fluid (CSF).

## Description of the problem

For the above-mentioned product LOT a labelling error occurred. The products were manufactured in May 2024 and have a shelf life of 3 years. The products can therefore be used until May 2027. However, the year of manufacture on the product label is 05/2025 and therefore the expiry date is 05/2028.

**Correct is only: Manufacturing in May 2024 with a shelf-life to May 2027**

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## Hazard giving rise to the problem

The risks connected to the mentioned problem is that the product might be used after the stated shelf-life. After the shelf-life is exceeded the sterility of the product cannot be guaranteed by Spiegelberg.

## Probability of problem arising

The probability of the product being unsterile after the shelf life is exceeded, cannot be determined. Only the mentioned LOT and product is affected.

## Predicted risk to the patient

If the product is used in an unsterile condition, it may lead to a higher risk of infection of the patient.

## Advice on action to be taken by the user

In order to mitigate the potential risk for the patient, all products from the mentioned LOT need to be discarded. Spiegelberg will provide replacement products, as soon as possible.

For a quick and coordinated distribution please follow these steps:

1. Please read this Field Safety Notice and all attachments carefully.

2. Please check if you have products in the affected LOT.

3. Please complete the customer response form (Att.01) and return it to Spiegelberg by post or fax. Please return the products of the affected batch to Spiegelberg. You can indicate on the reply form how many products you have sent in. Spiegelberg will replace the specified number of products. If it is not possible to return the products, we will send you a proof of destruction for the affected products.

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## Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Spiegelberg GmbH & Co. KG would like to apologize for any inconvenience caused and thanks you for your kind support. Please contact us in case of any questions.

Phone +49 40 790 178 – 20
Fax +49 40 790 178 – 10
Email sales@spiegelberg.de

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Kind regards,

Yves Eicke
Director Quality Management & Regulatory Affairs

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# Customer Reply Form – Att.01

| **1. Field Safety Corrective Action (FSCA) information** | |
|---|---|
| FSCA Reference number | **CMP-202407002** |
| FSCA Date | **16.07.2024** |
| Product/ Device name | **Silverline® Ventricular Catheter 8F** |
| Product Code(s) | **EVD30.010.02** |
| Batch/Serial Number (s) | **330 0 0137 24** |

| **2. Customer Details** | |
|---|---|
| Healthcare Organisation Name | |
| Organisation Address | |
| Department/Unit | |
| Shipping address if different to above | |
| Contact Name | |
| Title or Function | |
| Telephone number | |
| E-Mail | |

It is important that your organisation takes the actions detailed in the Field Safety Corrective Action (=FSCA) and confirms that you have received the FSCA.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Please see second page!

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| 3. Customer action undertaken on behalf of Healthcare Organisation | | |
|---|---|---|
| ☐ | I confirm receipt of the Field Safety Corrective Action and that I read and understood its content. | Customer to complete or enter N/A |
| ☐ | The information and required actions have been brought to the attention of all relevant users and executed. | Customer to complete or enter N/A |
| ☐ | I have discarded all products of the concerning LOT. If, yes how many were discarded. | Customer to complete or enter N/A |
| ☐ | I have sent all products of the concerning LOT to Spiegelberg. If, yes how many were sent. | Customer to complete or enter N/A |
| ☐ | I do not have any affected products. | Customer to complete or enter N/A |
| ☐ | I have a query please contact me. | Customer to enter contact details if different from above and brief description of query |
| Print Name | | Customer print name here |
| Signature | | Customer sign here |
| Date | | |

| 4. Return acknowledgement to sender | |
|---|---|
| E-Mail | sales@spiegelberg.de |
| Customer Helpline | +49 40 790178 20 |
| Postal Address | See first page |
| Webportal | http://www.Spiegelberg.de |
| Fax | +49 40 790 178 – 10 |
| Deadline for returning the customer reply form | 17.08.2024 |