Spiegelberg
Technology for brains

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

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Ref. Spiegelberg	Ref. BfArM
CMP-202311002	Fall-Nr. 35137/23

Hamburg, 22.11.2023

Urgent Information for Field Safety Corrective Action

concerning:

Spiegelberg Silverline® Ventricular Catheter 6F
AN: EVD30.020.02
LOT: 3300007820

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 6F. 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 6F**". Only the LOT 3300007820 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 have two labels on the outer packaging with different manufacturing and shelf-life dates. One label states manufacturing in April 2020 with a shelf-life to April 2023, the other label states manufacturing in April 2021 with a shelf-life to April 2024.

Correct is only: Manufacturing in April 2020 with a shelf-life to April 2023

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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 discard the affected products, fill out the customer reply form (Att.01) and send it back to Spiegelberg via mail or fax. In the customer reply form, you can state how many products you need replaced. Spiegelberg will send the requested number of products to you.

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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-202311002**
FSCA Date	**22.11.2023**
Product/ Device name	**Silverline® Ventricular Catheter 6F**
Product Code(s)	**EVD30.020.02**
Batch/Serial Number (s)	**3300007820**

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 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	15.12.2023