Spiegelberg:
Technology for brains

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

Spiegelberg GmbH & Co. KG
Tempowerkring 4
21079 Hamburg
Germany

Telefon: +49 40 790178-0
Fax: +49 40 790178-10

info@spiegelberg.de
www.spiegelberg.de

Ref. Spiegelberg	Ref. BfArM
CMP-202211001	Fall-Nr. 31936/22

Hamburg, 06.12.2022

Urgent Field Safety Notice

For Spiegelberg Probes with tunneling:

“Silverline® Ventricular Probe 8F” (SND13.1.14)
“Silverline® Ventricular Probe 10F” (SND13.1.15)
“True Tunneling Intraventricular Probe 7F” (SND13.1.13TT)
“True Tunneling Intraventricular Probe 9F” (SND13.1.13XLTT)
“Probe 3PN with Trocar” (SND13.1.54)

Dear valued Spiegelberg Customer,

As a precautionary measure, Spiegelberg GmbH & Co KG (subsequently: Spiegelberg) is voluntarily providing, in the form of this notice, a customer information regarding corrective action in the field for the Spiegelberg ICP-probes with tunnelling. The affected products are also listed in Attachment 1 (=Att.01).
According to our documentation, you received one of the possibly affected probes. 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 “**Probe 3PN with Trocar”** however all sterile Spiegelberg Probes with tunneling are potentially affected. For a detailed list and affected serial-numbers please see Att. 01. The ICP-probes are used for the measurement of intracranial pressure (ICP) in adults and all ventricular probes for the drainage of cerebrospinal fluid (CSF), as well.

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

Description of the problem

All the above-mentioned products can be tunneled away from the operation site, with the help of a trocar. After tunnelling, the air lumen of the probe is connected to an extension tube that in turn is connected to the Spiegelberg-ICP-Monitor.

To connect the extension tube, a securing nut (see Figure 1, (2)) is pushed on the probeside-connector (see Figure 1, (1)). The securing nut contains two plates that allow the probeside-connector to snap securely in place inside the securing nut.

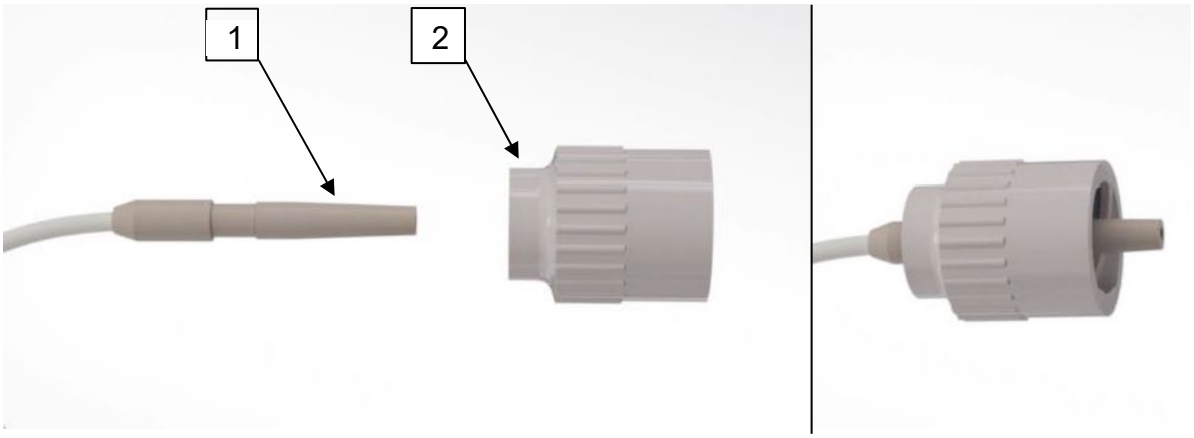


Figure 1: left: probeside-connector (1) and securing nut (2); right: finished connection

Due to a slowly progressed joining-tool wear, it is possible that the two plates inside the securing nut might break free of the securing nut (see Figure 2).

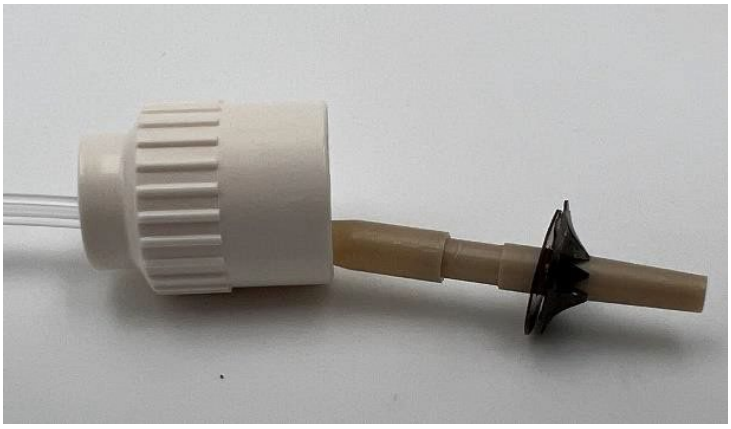


Figure 2: Failed connection

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

Hazard giving rise to the FSCA

The risk for a failure of this connection was identified and assessed within the Spiegelberg risk management process. Two hazardous situations were identified:

1. The probe is placed and tunneled. The user tries to make the connection between the securing nut and the probeside-connector. The connection fails (as shown in Figure 2) and cannot be made. The two plates and the securing nut can be removed from the probeside-connector, a new securing nut needs to be used. Therefore, a new product needs to be opened.
2. The probe is placed and tunneled. The user tries to make the connection between the securing nut and the probeside-connector. The connection fails (as shown in Figure 2) and cannot be made. The two plates and securing nut cannot be removed from the probeside-connector, the probe needs to be removed and a new probe must be placed and tunneled.

Probability of problem arising

Spiegelberg already performed extensive investigation into the probability of this problem. Based on these investigations and the number of complaints Spiegelberg received so far, the probability of the problem arising is ~0,5 (in words: “occasionally – occurrence is possible”).

Predicted risk to patient

In case the connection fails, a new product needs to be opened. The operation will be prolonged (few minutes).

Further background on issue

Spiegelberg received 4 complaints only for the probe 3 with trocar on this issue within a short period of time. In none of the complaints an effect on the patient condition was reported. This was recognized as a trending mode of failure anyway and further investigated.

Upon investigation, it was found that a slowly progressed joining-tool wear, that was not identified within the maintenance process, caused the weakening of the securing nut.

Corrective actions are currently being taken by Spiegelberg. I.E.:

a. Update of the manufacturing process, tools, and standard operating procedures.
b. Update of the concerning tool-maintenance process.
c. Update of the risk assessment.

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

Advice on action to be taken by the user

In order to mitigate the potential risk for the patient, Spiegelberg will provide double packed and sterile security nuts as replacement parts. These security nuts will originate from the updated manufacturing process.

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 serial number range (see Att.01).

3. Please fill out the customer reply form (Att.02) and send it back to Spiegelberg via mail or fax. In the customer reply form, you can decide how many security nuts you need replaced. Spiegelberg will send the requested number of security nuts to you.

4. For distributors: Please store and send the replacement security nuts within the affected product packaging.

5. Please use the replacement security nut for all operations with affected products and discard the security nut from the original product packaging.

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

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.

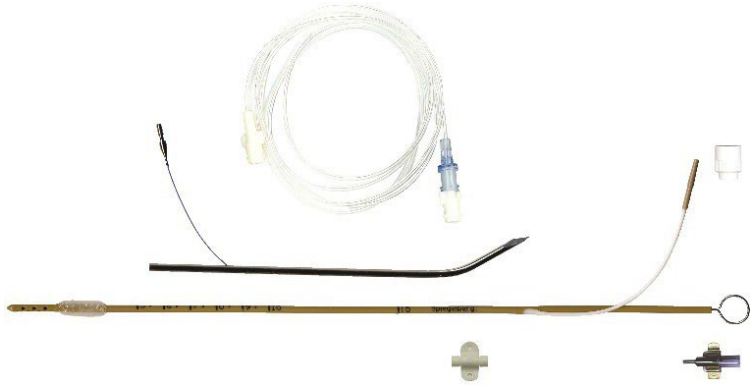
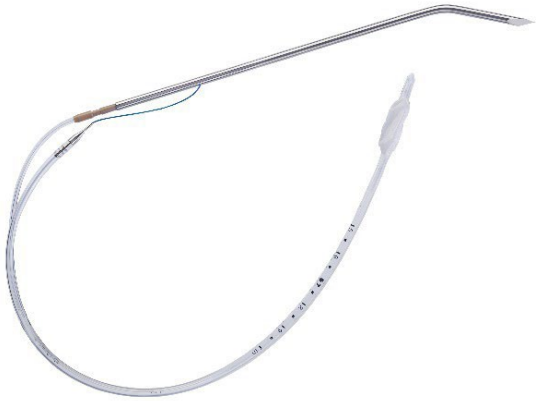
Kind regards,

…
Director Quality Management & Regulatory Affairs

Spiegelberg:
Technology for brains

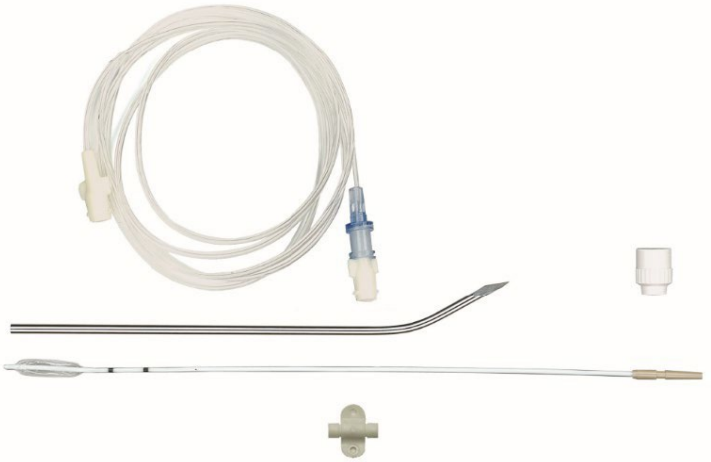
Att. 01 – URGENT FIELD SAFETY NOTICE
DEVICE TYPES

Table 1: Affected Devices

Comercial Name	Device Model (Articlenumber)	Potentially Affected Serial Numbers (SN)	Device Picture
Tunneling Silverline® Ventricular Probe 8F	SND13.1.14	**First SN: 2698** **Last SN: 3173**	
Tunneling Silverline® Ventricular Probe 10F	SND13.1.15 (Identical to SND13.1.14, only different diameter of the tubing)	**First SN: 6529** **Last SN: 7487**	
True Tunneling Intraventricular Probe 7F	SND13.1.13TT (Identical contents to SND13.1.14, not all accessories shown)	**First SN: 945** **Last SN: 1008**	
True Tunneling Intraventricular Probe 9F	SND13.1.13XLTT (Identical to SND13.1.13TT, only different diameter of the tubing)	**First SN: 1302** **Last SN: 1387**	

Spiegelberg:
Technology for brains

Att. 01 – URGENT FIELD SAFETY NOTICE
DEVICE TYPES

Comercial Name	Device Model (Articlenumber)	Potentially Affected Serial Numbers (SN)	Device Picture
3PN Probe with Trocar	SND13.1.54	**First SN: 12111** **Last SN: 17386** **<u>NOT Affected:</u>** **16987 – 17309**	

Spiegelberg:
Technology for brains

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

Spiegelberg GmbH & Co. KG
Tempowerkring 4
21079 Hamburg
Germany

Telefon: +49 40 790178-0
Fax: +49 40 790178-10

info@spiegelberg.de
www.spiegelberg.de

Customer Reply Form – Att.02

1. Field Safety Notice (FSN) information	
FSN Reference number	CMP-202211001
FSN Date	06.12.2022
Product/ Device name	Spiegelberg Probes with Tunneling
Product Code(s)	1. SND13.1.54 2. SND13.1.13TT 3. SND13.1.13XLTT 4. SND13.1.14 5. SND13.1.15
Batch/Serial Number (s)	See Att. 01

2. Customer Details	
Account Number	
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 FSN and confirms that you have received the FSN.

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

Please see second page!

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

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice 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
☐	Other Action (Define): Please fill out the number of security nuts that need to be replaced.	Customer to complete or enter N/A
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	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	03.01.2023