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Urgent safety information

Voluntary recall of

Spiegelberg GmbH & Co. KG´s **Silverline® Lumbar Drainage Catheter; REF: ELD33.010.02**

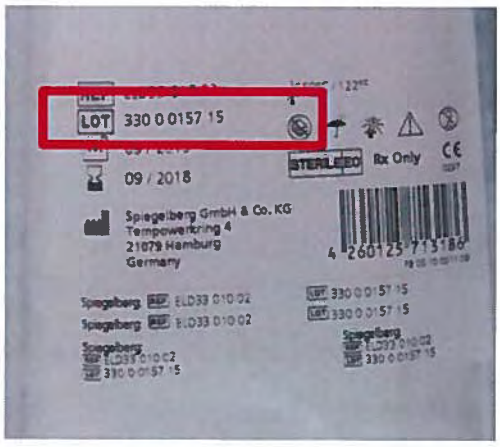
15. February 2016

Dear users,

With this notification Spiegelberg GmbH & Co. KG would like to inform you of a voluntary recall of product Silverline® Lumbar Drainage Catheter; REF: ELD33.010.02 with **LOT** number **330 0 0175 15** only.

Identification of affected products

The product LOT number can be identified on the product label, located on both the external packaging as well as the sterile bag.



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Problem description

The external lumbar drainage catheter is used for the drainage of cerebrospinal fluid (CSF) for diagnostic and therapeutic purposes for up to 30 days. In the unlikely case of improper folding of the instructions for use accompanying the product, excessive pressure may be exerted on the catheter, thereby affecting its drainage properties.

Risks

Potential risks are an insufficient drainage of CSF and, in consequence, an incorrect or inadequate diagnosis or treatment.

Actions

In the context of an unlikely but theoretically possible risk to the concerned product, Spiegelberg GmbH & Co. KG have decided, in full awareness of their duty of care and according to our quality philosophy, not to damage the confidence of patients in the safety of our products.

Products affected by this recall are to be quarantined immediately and returned to the following address:

Spiegelberg GmbH & Co. KG
Tempowerkring 4
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The affected products will be immediately exchanged free of charge.

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Distribution of Information described above

Please make sure that all users of products specified above in your organization and all other relevant personnel are made aware of this urgent safety information. In case you have forwarded said products to any third party, please forward a copy of this information or inform the contact person below.

Please keep this information at least until this corrective action has been completed.

The German Federal Institute for Drugs and Medical Devices has received a copy of this urgent safety information notification.

Spiegelberg GmbH & Co. Kg apologizes for any inconvenience and thanks you for your support with the execution of this corrective action. In case of any questions regarding this corrective action or affected products, please contact us directly.

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e-mail sales@spiegelberg.de.

Signature: [redacted]