

Spiegelberg:

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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.



Commerzbank
Konto 1 966 133 00
BLZ 200 800 00
IBAN: DE 77 2008
0000 0196 6133 00
SWIFT-BIC:
COBADEFF

Hypovereinsbank
Konto 16 34 310
BLZ 200 300 00
IBAN: DE 90 2003
0000 0001 6343 10
SWIFT-BIC:
HYVEDEMM

Volksbank Stade
Konto 100 33 00 900
BLZ 241 910 15
IBAN: DE 43 2419
1015 1003 3009 00
SWIFT-BIC:
GENODEF1SDE

Postgiro Hamburg
Konto 3249 203
BLZ 200 100 20
IBAN: DE 34 2001
0020 0003 2492 03
SWIFT-BIC:
PBNKDEFF

Spiegelberg
GmbH & Co. KG
Registergericht:
Hamburg HRA 81393
Ust. Identnr.:
DE118251415
Steuernummer:
47/660/00393

Persönlich haftende
Gesellschafterin:
Spiegelberg
Medizintechnik GmbH
Hamburg
Geschäftsführer:
Frank Sodha
Ingo Distel
Registergericht:
Hamburg HRB 46 157



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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
21079 Hamburg
Germany

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.

Telephone +49 40 790 178 – 20

Fax +49 40 790 178 – 10

e-mail sales@spiegelberg.de.

Signature:



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