

Fehling Instruments GmbH & Co KG
Hanauer Landstr. 7A
63791 Karlstein/Germany
Phone: +49 (0) 61 88 - 95 74-42
Fax: + 49 (0) 61 88 - 95 74-46

FEHLING INSTRUMENTS GmbH & Co.KG - Hanauer Landstr. 7A - 63791 Karlstein

4. April 2023 / BA
esther_bauer@fehling-instruments.de
www.fehling-instruments.de

FSN No. 23-005 Rev. 01
BfArM No. 09430/23

Urgent safety information
STOP OF USE
regarding
CEBOTARI Universal Sternal Spreader

Identification of affected medical devices:

REF: MQL-1
Description: CEBOTARI Universal Sternal Spreader

Description of the problem including the identified cause:

One of our customers informed us that after reprocessing the MQL-1 CEBOTARI Universal Sternal Spreader, contamination appeared on the ball thrust pieces:

After cleaning and disinfection of the spreader frames, impurities were noticed on the ball thrust pieces during the functional test. The contamination was detected after inserting and moving the spreader blades.

The ball of the ball thrust piece is installed in a cylindrical cavity in the spreader frame in such a way that the ball closes the cylindrical opening as soon as no pressure is applied to the ball. It is believed that abrasion or other debris accumulates on the surface of the ball or in the cylindrical cavity and is carried outward by the movement of the spreader blades and then accumulates around the ball thrust pieces on the spreader frame.

At this time, it is not clear whether only individual spreader frames, specific batches or all CEBOTARI Universal Sternal Spreaders are affected and what type of contamination is involved.

Seat:
Hanauer Landstr. 7A
63791 Karlstein/Germany
AG Aschaffenburg - HRA 4339

General Partner:
Fehling Verwaltungs GmbH - AG Aschaffenburg - HRB 9164
Registered office: Hanauer Landstr. 7A - 63791 Karlstein/Germany
Managing Director: Gerald Fehling u. Ulrike Lindner

Bank details:
IBAN: DE47 6435 0070 0008 5109 32
BIC: SOLADES1TUT
Tuttlingen District Savings Bank

What measures are to be taken by the addressee?

To avoid risks to the patient, it is mandatory to observe the following instruction:

The MQL-1 CEBOTARI Universal Sternal Spreader must not be used until the cause has been clarified and eliminated.

Measures taken by FEHLING INSTRUMENTS GmbH & Co. KG

FEHLING INSTRUMENTS GmbH & Co. KG will rebuild the affected MQL-1 CEBOTARI Universal Sternal Spreaders to prevent contaminants from accumulating in the cavity of the spreader frame.

Disclosure of the information described herein:

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Information.

If you have given the products to a third party, please forward a copy of this information or inform the contact person indicated below.

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

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact:

If you have any questions about the process, please contact the person below:

FEHLING INSTRUMENTS GmbH & Co. KG
Hanauer Landstr. 7A
63791 Karlstein
Germany
www.fehling-instruments.de

Esther Bauer
Tel.: +49 6188-95740
vigilance@fehling-instruments.de

Kind regards

FEHLING INSTRUMENTS GmbH & Co. KG

Esther Bauer
Quality Management Representative

CONFIRMATION FORM	
Please return by e-mail to vigilance@fehling-instruments.de	
FSN NO.:	23-005 – Rev. 01
FSN Date:	2023-03-30
Product	MQL-1 CEBOTARI Universal Sternal Spreader
CUSTOMER	
Name	
Address	
Contact	
Phone number	
Email	
Measures to be carried out by the customer	
<input type="checkbox"/>	I acknowledge receipt of the FSN and confirm that I have read and understood its contents.
<input type="checkbox"/>	I have performed all the actions required by the FSN.
<input type="checkbox"/>	The information and required actions were brought to the attention of all relevant users and implemented.
Name	
Date	
Signature	

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7. Juni 2023 / BA
esther_bauer@fehling-instruments.de
www.fehling-instruments.de

FSN No. 23-005 Rev. 02
BfArM No. 09430/23

Urgent safety information
RECALL / REPLACEMENT
regarding
CEBOTARI Universal Sternal Spreader

Identification of affected medical devices:

REF: MQL-1
Description: CEBOTARI Universal Sternal Spreader

Description of the problem including the identified cause:

After a customer informed us that after reprocessing the MQL-1 CEBOTARI universal sternal spreaders, contamination appeared on the ball thrust pieces, we solved the problem by changing the design of the spreader arms.

The new spreader arms are designed in such a way that the ball thrust pieces are relieved of pressure during use and therefore, the balls close the cylindrical opening.

What measures are to be taken by the addressee?

The two spreader arms of the MQL-1 CEBOTARI Universal Sternal Spreader must be replaced with the newly designed spreader arms. The old spreader arms must no longer be used and must be disposed of.

In consultation with FEHLING INSTRUMENTS GmbH & Co. KG the replacement of the spreader arms can be done by the customer as well as by return to FEHLING INSTRUMENTS GmbH & Co. KG.

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Measures taken by FEHLING INSTRUMENTS GmbH & Co. KG

FEHLING INSTRUMENTS GmbH & Co. KG will replace the spreader arms of the affected MQL-1 CE-BOTARI universal sternum spreaders so that no impurities can accumulate in the cavity of the spreader frame.

The replacement will take place successively in the period **from xxx to xxx** and will be organized by the internal service department.

Disclosure of the information described herein:

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Information.

If you have given the products to a third party, please forward a copy of this information or inform the contact person indicated below.

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

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact:

If you have any questions about the process, please contact the person below:

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Esther Bauer
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vigilance@fehling-instruments.de

Kind regards

FEHLING INSTRUMENTS GmbH & Co. KG

Esther Bauer
Quality Management Representative

CONFIRMATION FORM	
Please return by e-mail to vigilance@fehling-instruments.de	
FSN NO.:	23-005 – Rev. 02
FSN Date:	2023-06-07
Product	MQL-1 CEBOTARI Universal Sternal Spreader
CUSTOMER	
Name	
Address	
Contact	
Phone number	
Email	
Measures to be carried out by the customer	
<input type="checkbox"/>	I acknowledge receipt of the FSN and confirm that I have read and understood its contents.
<input type="checkbox"/>	I am returning the MQL-1 CEBOTARI Universal Sternal Spreader for replacement of the spreader arms to FEHLING INSTRUMENTS GmbH & Co. KG or have already sent it back.
<input type="checkbox"/>	I will replace the spreader arms on site and assure that I will dispose of the old spreader arms and not use them again.
<input type="checkbox"/>	The information and required actions were brought to the attention of all relevant users and implemented.
Name	
Date	
Signature	