
Urgent Safety Information
neon³™ universal OCT spinal stabilization
Recall of neon³ rods

2023-03-27

Sender

Ulrich GmbH & Co KG Buchbrunnenweg 12 89081 Ulm

Addressee

Users of the neon³™ universal OCT spinal stabilization system.

Identification of the medical devices concerned

Individual batches of neon³ rods are affected

Article number	Article description	Batch number
CS 3910-030	Rod, titanium alloy, Ø 4.0 mm, length 30 mm	U037178
CS 3910-025	Rod, titanium alloy, Ø 4.0 mm, length 25 mm	U037171
CS 3910-035	Rod, titanium alloy, Ø 4.0 mm, length 35 mm	U037170
CS 3910-140	Rod, titanium alloy, Ø 4.0 mm, length 140 mm	U036810
CS 3913-40-05	OC rod, titanium alloy, Ø 4.0 mm,	U037402
CS 3910-100	Rod, titanium alloy, Ø 4.0 mm, length 100 mm	U037181
CS 3910-065	Rod, titanium alloy, Ø 4.0 mm, length 65 mm	U037179
CS 3910-120	Rod, titanium alloy, Ø 4.0 mm, length 120 mm	U038542
CS 3910-160	Rod, titanium alloy, Ø 4.0 mm, length 160 mm	U037293
CS 3910-01-055	Rod, titanium alloy, Ø 4.0 mm, curved,	U037864

Description of the problem including the identified cause

During the production of neon³ rods, deviations from the specification were identified in a batch of raw material. Any defect in the material can lead to a reduction in the mechanical strength of the rod. Since we cannot exclude one hundred percent that this reduction is safety-relevant for the application of these products, we are carrying out a product recall as a precautionary measure.

What measures are to be taken by the addressee?

We are conducting a preventive recall of the products. Please identify the products you have in circulation and return them to us. There is no market feedback on implant failure or other problems with the affected products. We currently see no reason to issue additional follow-up recommendations for patients already supplied with these products.

Passing on the information described here

Please ensure that all users of the above products and other persons to be informed are made aware of this Urgent Safety Information. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below. Please keep this information at least until the measure has been completed. The national health authority has received a copy of this "Urgent Safety Information".

Please confirm receipt of the letter and implementation of the measures within **10 working days** using the attached Customer Feedback document.

For queries please contact

Ulrich GmbH & Co. KG
Buchbrunnweg 12
89081 Ulm
Germany

Ms Jennifer Dygrin

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vigilance@ulrichmedical.com

We thank you for your support and cooperation and apologise for any inconvenience that may be caused.

With kind regards

Ulrich Medical

A handwritten signature in blue ink, appearing to read "A. Hilzenbecher", with a faint "Ulrich Medical" watermark visible in the background.

Andreas Hilzenbecher
Person responsible for regulatory compliance

Appendix 1 - Customer feedback

Customer feedback

1. Urgent safety information	
FSN reference number	I-00404
FSN Date	27 March 2023
Product name	Neon ³ universal OCT spinal stabilization
Article numbers	Neon ³ rods CS 3910-XX

2. Measures implemented at the client			
<input type="checkbox"/>	I hereby confirm that I have read and understood the attached safety information.		
<input type="checkbox"/>	This safety information has been forwarded to the relevant bodies within the organisation.		
<input type="checkbox"/>	I confirm that I have implemented the measures to be taken accordingly and that the following items have been returned.		
Amount	Article number	Batch number	Amount returned
<input type="checkbox"/>	None of the affected products are available any more.		

3. Customer data	
Name of the health facility	
Name	
Signature	
Date	

4. Acknowledgement back to the sender	
E-mail	vigilance@ulrichmedical.com
Fax	+49 (0)731 9654-2802
Return deadline for customer feedback	07 April 2023

It is important that your organisation takes the actions listed in the FSN and confirms that you have received the FSN.

Your organisation's response is the evidence we need to monitor the progress of corrective action.