**ulrich GmbH & Co. KG** I Buchbrunnenweg 12 I 89081 Ulm

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# Urgent Safety Information

# neon³™ universal OCT spinal stabilization

# Recall of neon³ rods

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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
Buchbrunnenweg 12
89081 Ulm
Germany

[redacted]

Tel.:+49 (0)731 9654-2308
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

[redacted]
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 | Neon³ universal OCT spinal stabilization |
| Article numbers | Neon³ rods CS 3910-XX |

| 2. Measures implemented at the client | | | |
|---|---|---|---|
| ☐ | I hereby confirm that I have read and understood the attached safety information. | Please tick or cancel with N/A | |
| ☐ | This safety information has been forwarded to the relevant bodies within the organisation. | Please tick or cancel with N/A | |
| ☐ | 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 |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| ☐ | None of the affected products are available any more. | Please tick or cancel with N/A | |

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

| 4. Acknowledgement back to the sender | |
|---|---|
| E-mail | vigilance@ulrichmedical.com |
| 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.