

AHi/09.10.2019

**Urgent Safety Information - Product Recall**

**neon<sup>3</sup>™ universal OCT spinal stabilization**

**CS 3926-03 „Drill 1 for CS 3902, CS 3903, CS 3904“ from production batch  
BE2060391619**

**Internal Reference I-00316**

Dear Customers,

We have identified a production defect in a drill from the neon<sup>3</sup> system as part of a complaint. The error can be restricted to the production batch BE2060391619. Therefore we will recall all "Drill 1 for CS 3902, CS 3903, CS 3904" with the article number CS 3926-03 of the production batch BE2060391619 from the market.

In this context we ask you for your assistance!

With this **safety information** we inform you about the following:

- What exactly the problem is.
- Which measures must be taken by the customer/user to avoid endangering the patients.
- What measures Ulrich Medical has planned to take to solve the problem.

The **safety information** contains information on the identification of the articles concerned and instructions on the measures to be taken. Please follow the information in the "**What action should you take**" section of this document.

**Identification of the medical devices concerned**

CS 3926-03 - Drill 1 for CS 3902, CS 3903, CS 3904

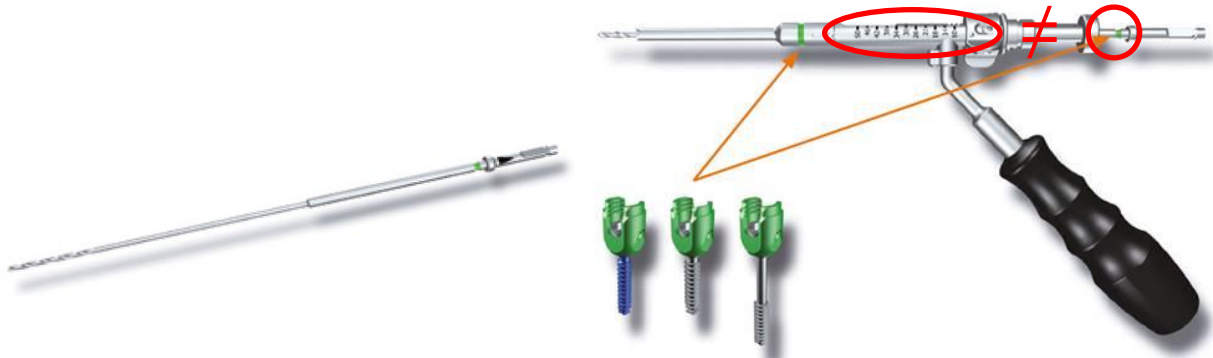
Production batch affected:

BE2060391619

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### Problem description

Due to a production error, the drill cannot be fully inserted into the CS 3929-05 drilling aid. Thus the actual drilling depth is approx. 3mm less than shown on the drilling aid CS 3929-05.



### Potential risk

If surgery is performed according to the steps of the neon<sup>3</sup> system surgical technique, the screw length is determined using the special depth gauge CS 3930. In this case, there is no risk for the patient. If, however, the screw length is incorrectly selected solely on the basis of the setting on the drill guide, this may lead to an incorrect choice of screw length. This may have a negative effect on the treatment success or lead to a direct risk for the patient.

### Which measures are to be taken by you?

In order to avoid the possible complications described above, we recall all drills still in use from production batch BE2060391619. Please send the affected article with the enclosed return form to the address below. You will immediately receive a free replacement.

Please confirm receipt of the letter with the attached document as soon as possible:

### Acknowledgement of receipt Safety Information

### Disclosure of the information described here

Please ensure in your organisation that all users of the above product and other persons to be informed are aware of this safety information.

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

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

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**Contact person:**

In case of any questions, please contact

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This corrective measure has already been reported to the competent authorities.

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

Best regards

Ulrich Medical



Andreas Hilzenbecher  
Safety Officer Implant Systems