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Internal Reference number: I-00227

Date

Urgent Safety Information

regarding

Surgical Technique uCentum™ comprehensive posterior system open and
percutaneous

CS 3801-01 – Locking Screw – All LOTs

Dear Customer,

Hereby we inform you about:

- Description of the product information
- Which action has to be taken by customer/user to avoid risks for the patient
- Which actions are planned by ulrich medical to solve the problem

This **urgent safety information** contains instructions for the medical device mentioned above.

Please follow the information in the section „**Which actions have to be taken by the addressee**” in this document.

Identification of the referred medical device:

Name of System – Article-No.– Article Description:

uCentum™ comprehensive posterior system – CS 3801-01 – Locking screw

Serial-/LOT No.:

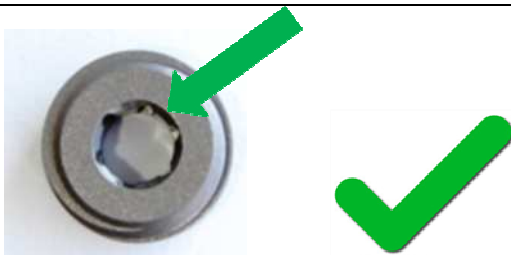
All LOTs

Note: The pre-fixation locking screws CS 3801-02 are not the subject of this information

Description of the problem, including the cause identified:

We find out that the locking screw CS 3801-01 fit to both sides to the screwdriver tip for locking screws, self-retaining CS 3851-01. The fixation however is only correct from the top side of the locking screw, being easily identified. Therefore the uCentum surgical technique open and percutaneous in the step screwing in the locking screw CS 3801-01 in "instrumentation using polyaxial and monoaxial screws" will be specified.

Top side of the locking screw
→ correct insertion, visible inner hexagon

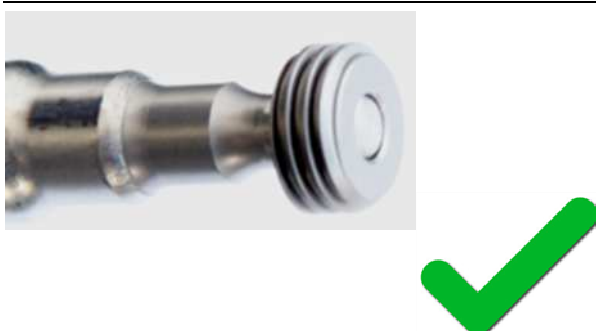


Under side of the locking screw
→ incorrect insert, no visible inner hexagon

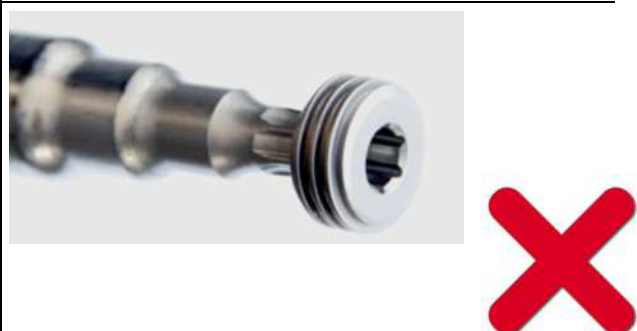


If the locking screw CS 3801-01 is added from the top side with the visible inner hexagon, the locking screw can be mounted on the entire length of the screwdriver tip for locking screws, self-retraining CS 3851-01 (see left figure below). By putting on the locking screw from the underside, the screw can obviously only mounted to a small part on the screw driver tip. (see right figure below).

Adding from the correct side
→ topside



Adding from the incorrect side
→ underside



Potential risk:

As a result of mounting the locking screw from the underside it would not possible to insert and position the locking screw properly into the screw head with the self-retaining screwdriver for locking screws CS 3851-01. In consequence, at the final tightening step of the locking screw with the screwdriver 3851-02 combined with the T-handle torque CS 7146 the screwdriver “spins”, because the screwdriver tip cannot be inserted into the inner hexagon of the locking screw. By this fact latest, the user realizes the false insertion. This situation has to be corrected by a new correct positioning and insertion of the locking screw.

Which actions have to be taken by the addressee?

All users have to get knowledge about this safety information to the correct orientation of the locking screw CS 3801-01 together with the screwdriver for locking screws, self-retraining CS 3851-01.

Which actions are planned by ulrich medical to solve the problem?

Surgical Technique of uCentum™ comprehensive posterior system open and percutaneous will be specified, to inform in future all users about the correct handling.

Please confirm the receipt of the letter with the attached document “**Confirmation of receipt urgent safety Information**”.

Please refer in the subject to our **internal reference number: I-00227**

Transmitting the information described here

Please make sure in your organization, that all users of the above named product and other relevant persons get knowledge of this **Urgent Safety Information**.

If you have delivered the product to third parties, please forward a copy of this information to them or inform the below named contact person.

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



Contact person:

For further information please contact:

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We apologize for any inconvenience this situation may have caused to you.

Best regards

Ulrich GmbH & Co. KG

Andreas Hilzenbecher

Safety Officer