

## Urgent Field Safety Notice (FSN)

### Locking cervical plates

<b>FSN No.:</b>	DBR.FSN - 01/2026
<b>Type of FSN:</b>	voluntary notification regarding the safety of the use of a medical device
<b>Commercial name of the affected product:</b>	Locking cervical plates acc. to Annex No. 1
<b>REFs of the affected product:</b>	acc. to Annex No. 1
<b>Attention:</b>	all current and potential users of orthopedic implants manufactured by ChM sp. z o.o.

#### Description of the problem

ChM has received a report from the market indicating that, during implantation of the locking cervical plate system, the locking spring rings became dislodged from the plate. In the reported case, the cervical plate, spring rings, and locking cervical screws were removed from the patient and replaced with a new cervical plate and screw set. The procedure was completed successfully. No prolonged surgical procedure, patient injury, or other adverse events were reported.

This Field Safety Notice (FSN) is being issued to remind users of the importance of strict adherence to the implantation procedure for the ChM locking cervical plate system, as described in the applicable surgical technique manual supplied with the device and available in its most current version on the ChM website: chm.eu.

#### Potential risks and adverse events

##### **1. The screw cannot be locked into the plate hole**

The dislodgement of the locking spring rings from the plate may prevent proper locking of the screw within the plate hole. It should be emphasized that, should a spring ring become loosened or dislodged from the plate, this condition can be identified intraoperatively by the surgeon. In such cases, the implantation procedure should be discontinued and the implant replaced with a new device to ensure correct functioning of the entire system. At the same time, it has been determined that, in cases where the screw has been correctly seated and securely locked within the plate hole, there is no increased risk of screw loosening or subsequent dislodgement of the locking spring ring.

##### **2. Prolongation of the surgical procedure**

Due to the identified potential risk of intraoperative dislodgement of the spring rings, the surgical procedure may be prolonged as a result of the need to remove the affected component and replace it with a new, properly functioning device.

As of the date of this Field Safety Notice, ChM sp. z o.o. has received one report related to this issue.

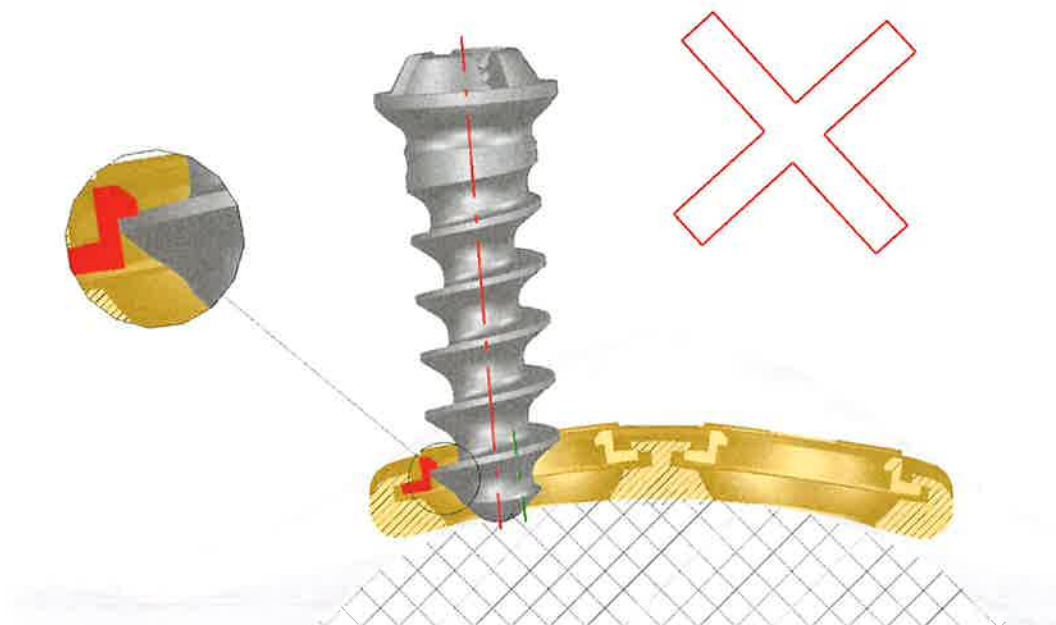
#### Advise on action to be taken by the user

Based on the analysis of information received from the market, ChM has determined that a product recall is not necessary at this time. The manufacturer considers that revision of the surgical technique document ST-29E-

2\_CHARSPINE\_SPINE-CERVICAL-PLATE and distribution of this Urgent Field Safety Notice to all affected hospital units and authorized distributors constitute an adequate corrective action.

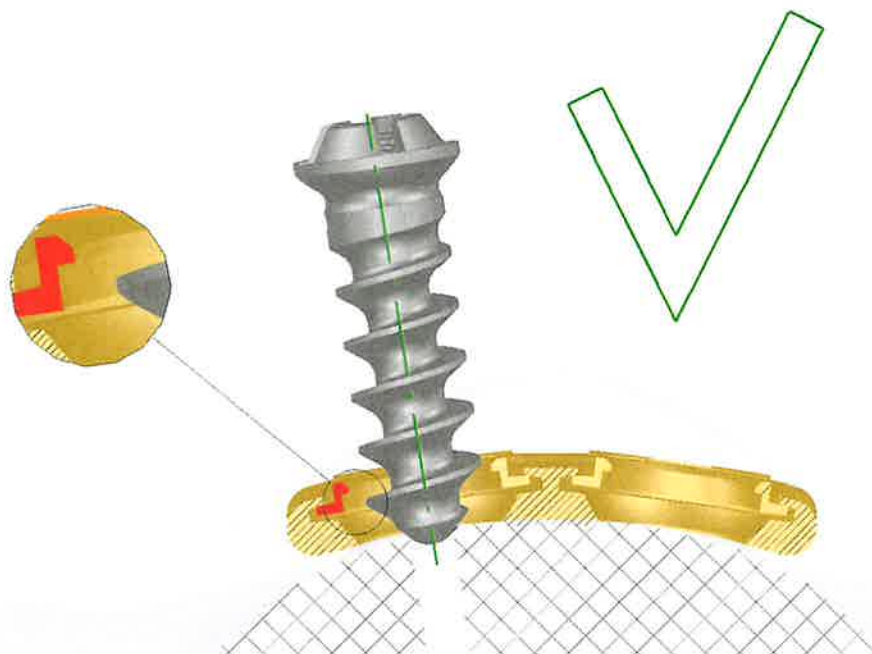
To further clarify the relevant surgical technique, the following information has been added:

**CAUTION:** When inserting the screws, particular care should be taken to ensure proper alignment and centering of the screw relative to the plate hole. **Off-axis insertion or displacement of the screw from the center of the plate hole may result in damage to, or dislodgement of, the securing ring located within the locking screw hole!** If elevation of the plate or displacement of the securing ring is observed during screw insertion, the insertion procedure should be stopped immediately. The screw should then be repositioned to achieve correct centering relative to the plate hole before reinserting it into the vertebral body.



*Fig. 1. An example of incorrect screw insertion*

To minimize the risk of screw displacement relative to the plate hole, the plate should be initially stabilized (see Sections 5.2, point 4 of the surgical technique), and a pilot hole should be prepared for each inserted screw (using a guide sleeve and a trocar according to the procedure described in chapter 5.3, point 5 of the surgical technique or using a guide sleeve and a drill according to chapter 5.4, point 6 of the surgical technique).



*Fig. 2. An example of correct screw insertion*

The above activities are aimed at ensuring the safe and correct use of products in accordance with their intended purpose.

If you have any questions regarding this Field Safety Notice, please contact us by email at: [sprzedaz@chm.eu](mailto:sprzedaz@chm.eu)

This notice should be forwarded to all individuals within your organization who need to be informed, as well as to any organization to which the affected devices have been transferred. Please ensure that awareness of this notice is maintained for an appropriate period of time to ensure the effectiveness of the corrective action.

The objective of ChM sp. z o.o. is to supply only products that comply with the highest quality standards and to provide the necessary support to ensure their safe and effective use.

Thank you for your cooperation.

Kind regards,

**ChM****ChM sp. z o.o.****RESEARCH AND Zbigniew  
DEVELOPMENT DIRECTOR | Murawski**  
signature

