

## Field Safety Notice Concerning the ERISMA LP EVO SCREW HEAD POSITIONER

11/05/2023

Clariance reference: 20230511\_MV

ANSM reference:

Dear Doctor, Vigilance Correspondent or Director of the establishment,

CLARIANCE has deemed it necessary to warn you of a risk linked to the disassembly of pedicle screw by using the "Screw Head Positioner" during surgery.

We bring to your attention the following information:

"We have detected a risk of disassembly of pedicle screw with the use of one of the instruments: the Screw Head Positioner (ref : 18719001, 18719002, 50719002).

This instrument is used to orientate and align the screw heads.

The risk assessment, based on our statistics prior to this incident, is a very low occurrence. In view of the latest tests carried out by our R&D department, we however feel it is necessary to inform all users of this risk.

Knowing that in such a case, the surgeon can use another instrument to orientate the screw head which is the Guiding Tube ref 18721005 or the Counter Torque ref 18721008 (both present in the Surgical Kit).

The root cause analysis has been completed. Preventive and corrective actions have been implemented to avoid the recurrence of the problem.

The risk for the patient is a loosening of the set screw which could migrate out of the screw head. In other words, there would be a loss of fixation stability, and therefore a loss of correction on at least one segment of the spine. This risk is limited by the symmetry of the assembly. What's more, the implants are biocompatible and radio-opaque.

We have described the various possible cases of screw disassembly using the head positioner:

Case 1	When the screw head is repositioned, the pad is removed from its position but does not disassemble the screw. The assembly is completed and held in place by the pressure of the rod and clamping screw.	No loosening of the set screw during post-operative inspection and normal monitoring. No or negligible impact on the stability of the assembly. The surgeon may notice disassembly if the Medical devices are removed during revision surgery.
Case 2	When the screw head is repositioned, the pad is removed from its position but does not disassemble the screw. The assembly is completed and held in place by the pressure of the rod and clamping screw.	On post-operative and/or follow-up X-rays, the surgeon observes a partial loosening of the set screw. This affects the stability of the assembly. The stem is free to translate on the segment concerned. Depending on the patient's symptoms (non-existent, pain, etc.) and the benefit/risk balance, the surgeon may decide to perform revision surgery.
Case 3	When the screw head is repositioned, the pad is removed from its position but does not disassemble the screw. The assembly is completed and held in place by the pressure of the rod and clamping screw.	On post-operative and/or follow-up X-rays, the surgeon observes migration of the clamping screw. The set screw has come out of the screw head and no longer locks the stem. The stability of the assembly is affected. The stem is free on the segment concerned. Depending on the patient's symptoms (no symptoms, pain, etc.) and the benefit/risk balance, the surgeon may decide to perform revision surgery.
Case 4	When the screw head is repositioned, the pad is removed from its position but does not disassemble the screw. The assembly is completed and held in place by the pressure of the rod and clamping screw.	In addition to the situations described in cases 1, 2 and 3, the surgeon may observe one or more fragments on the pedicle screws on post-operative X-rays and subsequent follow-up X-rays, suggesting that a pin on the screw pad has migrated, breaking off as the pad moves and the stem rests on it. Depending on the patient's symptoms (no symptoms, pain, etc.), the benefit/risk balance for the patient and the area of migration of the fragment, the surgeon may decide to perform revision surgery.



Pending a change in the design of the instrument to eliminate the risk and its replacement in the surgical KIT, you will find an appendix to the operating technique attached.

Please share this information within your Operating Room, Neurosurgery Department, Orthopedics Department, and any other function in your facility that needs to be aware of this FSN.

We remain at your disposal to provide you with any information that may help you.

To do so, please submit your request in writing to the Quality & Regulatory & Clinical Director to the following address: [m.hennequin@clariance-spine.com](mailto:m.hennequin@clariance-spine.com)

The ANSM has been notified of this safety information.

Please complete the attached form for our records, indicating that you have received this FSN and that it has been distributed within your institution. .

We thank you in advance for your cooperation and we apologize for the inconvenience caused by this action.

  
Quality & Regulatory & Clinical Director

**It is important that your institution confirm that you have received the FSN**

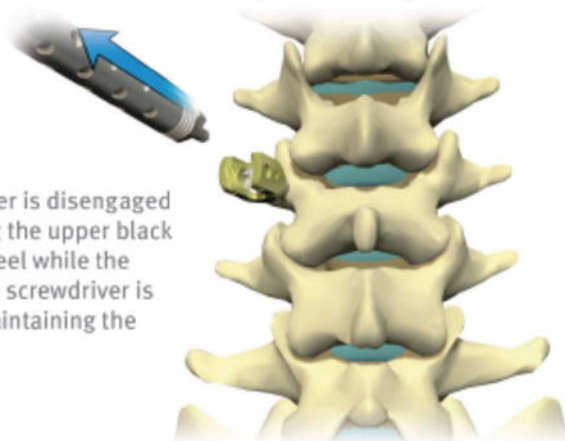
<b>Field Safety Notice Concerning the ERSMA LP EVO SCREW HEAD POSITIONER</b>	
Reference FSN	
Date of FSN	11/05/2023

<input type="checkbox"/> We confirm that we have taken note of this safety notice	
Name of the establishment	
Address	
Name/Function	
Phone	
Date and signature	

<b>Référence</b>	<b>Lot</b>	<b>Quantity</b>
18719001	B104I	
	C611X	
	C856F	
	D302F	
	D312F	
	D324F	
	G119 F	
	G704F	
	GA33F	
18719002	GA82F	
	IB06Z	
	K725K	
	KC27K	
	M2D7K	
	M371K	
	M3A1K	
	N136K	
	N180K	
50719002	I411U	

## REPLACES p. 9 of 30BROENV02 Surgical Technique

The screwdriver is disengaged by unscrewing the upper black tightening wheel while the rotation of the screwdriver is blocked by maintaining the handle.



If the screw is over-inserted or insufficiently inserted, its depth can be modified by using the **T20 wrench**.

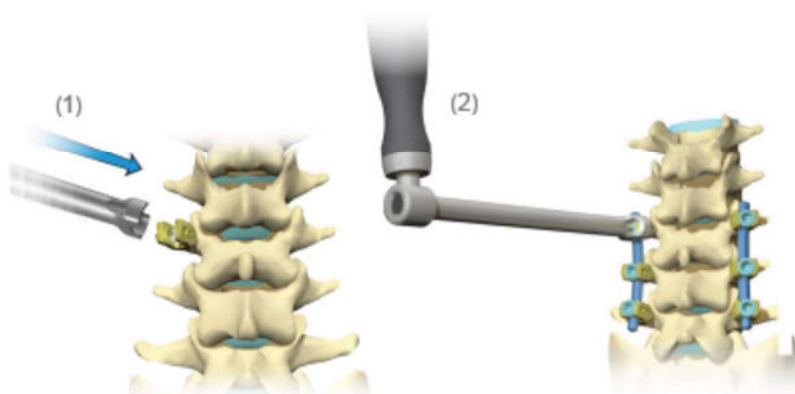
Radiological control is carried out to verify the position of the screws in the pedicles.

## Rod preparation

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**i** The *Erisma<sup>®</sup>-LP Evolution* system offers a range of pre-bent rods (30mm to 100mm). Longer rods are straight and require bending.

If desired, the guiding tube (1) or counter torque (2) may be used to orientate and align the screw heads.



If necessary, the **french bender** is used to fit the desired rod contour. The bender of the *Erisma<sup>®</sup>-LP Evolution* system offers several bending ranges.



18720000  
T20 WRENCH



18721005  
GUIDING TUBE



18721002  
COUNTER TORQUE



99750003  
FRENCH BENDER