Rev 1: April 2026
FSN/FSCA Ref: VR-26-01 (FBR-26-03-005)

Date: 08 Apr 2026

Urgent Field Safety Notice
Neuromate Head Holder
Risk of tight fit of pins

For Attention of: Neurosurgeons, Neurosurgical Theatre Staff, Medical engineers, Sterilisation personnel and Hospital Medical Device Safety Officer (MDSO)

Contact details
Renishaw Mayfield SARL Confidential business information Confidential business information Additional support is available from your field service representative

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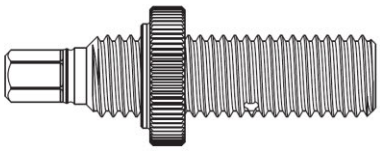
1. Information on Affected Devices	
	1. Device Type(s)*
	Head holder and head holder pins
	2. Commercial name(s)
	neuromate Head Holder Set; neuromate frameless head-holder pin
	3. Unique Device Identifier(s) (UDI-DI)
	03662724076586 (neuromate Head Holder Set) 03662724000246 (neuromate frameless head-holder pin)
	4. Primary clinical purpose of device(s)
	Used to immobilise head to perform frameless neurosurgical procedures in conjunction with the neuromate stereotactic robot
	5. Device Model/Catalogue/part number(s)
	001.0067 (neuromate Head Holder Set) 003.0149 (neuromate frameless head-holder pin)
	6. Affected serial or lot number range
	All devices are potentially affected

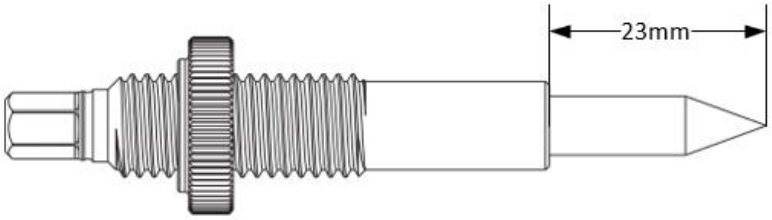
2. Reason for Field Safety Corrective Action (FSCA)	
	1. Description of the product problem
	Feedback from customers suggests that the fit of some of the pins into the pin carrier is too tight; the pins are difficult to fit into the carriers and difficult to remove once in. Pins may get stuck/jammed within the pin carriers of the neuromate head holder.  **Short pin carrier**  **Long pin carrier**  **O-ring**  **Pin**
	2. Hazard giving rise to the FSCA
	Several risks have been identified as a result: - Potential risk of damage to pin by having to use tools to remove, thus potentially compromising sterilisation - Potential risk of loss of sterility while trying to insert the pin - Potential risk of harm to the user by the sharp end of the pin when trying to insert - Potential risk of harm to user on sharp end of contaminated pin when attempting to remove

	- Potential risk of harm to patient if pin appears to be fully seated but "jumps" in seated position under load (i.e. during surgery after registration) - Potential risk of harm to patient if the pin carrier is overtightened and the skull is perforated as a result - Potential risk to delay of surgery - Observed risk of O-ring being retained in carrier when pin removed blocking next pin from seating fully **The key impact of risks on the patient is the movement of the pin in the carrier during surgery. This could lead to movement of the position of the patient's head in relation to the robot. Movement of a patient could result in a potential inaccuracy in the planned trajectory leading to harm. As with all neurosurgeries the impact of this inaccuracy is dependent on the surgical plan and the type of surgery being carried out. An additional impact of risk is perforation of the skull from overtightening of the pin carrier containing a pin, as there may be uncertainty regarding the proper seating of the pin in the carrier.** **The key impact of risk on the user is that the user could pierce their skin when inserting or removing the pin, potentially resulting in contamination between patient and user.** At this time, there have been no actual reported incidents of harm, this is based on feedback on potential issues.
	3. Probability of problem arising
	This is likely to occur at all centres, with a head holder, depending on the combination of pins and pin carriers used. All centres have more pins than necessary to conduct the surgery so suitable combinations should be possible to allow surgery to continue.
	4. Background on Issue
	At this time the root cause is believed to be an issue with the interface specification tolerance of the pins and the carriers which leads to a tight fit in some combinations of pin and carrier. This is more likely to occur where the pin is at the larger end of its specification, and the hole of the pin carrier is at the smaller end of its specification. The same pin may fit into another pin carrier which is in the larger end of its specification.

	3. Type of Action to mitigate the risk
	1. Action To Be Taken by the User
	☒ Identify Device ☒ On-site device inspection, before each surgery 1. On initial assembly, clinicians should test a pin and pin carrier combination for appropriate fit before attempting to fully insert the pin. Clinicians should take care not to use pin and pin carrier combinations which exhibit a tight fit as this has an increased risk of injury to the user during handling. 2. Clinicians and sterilisation personnel should use minimal force and minimal tooling to remove pins from pin carriers. Pins and pin carriers should be checked for damage as per the User Manual; damaged items should not be used. Damaged or stuck combinations of pins and pin carriers should not be used as these cannot be adequately cleaned and sterilised between patients. Please inform your local representative if you have damaged items and/or a pin/pin carrier combination which becomes stuck. Once pins are inserted in the pin carrier 1. Inspect the depth of each pin to ensure that they are seated correctly. There should be a maximum of 23mm of pin protruding from the carrier. Insert until the pin is correctly

seated, if this is not possible, do not use the combination of pin and pin carrier. The pin can be tried in another pin carrier to find a combination that is suitable.

2. Ensure that the patients head is stable in the head holder before carrying out the verification trajectory, this will reduce the risk of further movement once the patient is registered to robot space.



2. By when should the action be completed?

Before each surgery

3. Is customer Reply Required?

Yes - See form at the end of this communication

4. Action Being Taken by the Manufacturer

Short term
Your local service representative can provide additional support during use, if required. Please inform your representative should you encounter a pin/pin carrier combination which become stuck and they will be able to advise on a solution.

Longer Term
Manufacturing specifications are being reviewed and updated to ensure that this issue does not occur with future batches of pins and pin carriers.

Replacement items will be provided, when available, to eliminate the issue in the field. Your Field Service Engineer will action this.

	4. General Information	
	1. FSN Type	New
	2. Further advice or information already expected in follow-up FSN?	No
	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (as appropriate). Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer Reply Form

This response form is to confirm receipt of the enclosed Renishaw Mayfield Urgent Field Safety Notice VR26-01.

Please send a scanned copy of the completed form via email to: Confidential business information your local Renishaw representative or post the form back to Renishaw Mayfield SARL, Confidential business information

It is important that your organisation takes the actions detailed in the FSN and confirm that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions and inform the Regulatory Authorities.

Customer action undertaken on behalf of Healthcare Organisation	
☐	I confirm receipt of the Field Safety Notice and that I have read and understood its content.
☐	I understand the actions requested by the FSN.
☐	The information and required actions have been brought to the attention of all relevant users and executed.
Print Name	
On behalf of (Organisation name)	
Signature	
Date	