Smith & Nephew, Inc.
Global Field Actions
1450 Brooks Road
Memphis, TN 38116
Tennessee, USA

T: + 1 901 396 2121
T: 1 800 821 5700 (USA toll free)
www.smith-nephew.com

Smith+Nephew

<Recipients Address>

URGENT FIELD SAFETY NOTICE: Correction

Date Issued: 07-May-2024

Reference: C-2024-03

Legal Manufacturer: Blue Belt Technologies, Inc.

Concerned Devices: Real Intelligence CORI

Product No.	Description	Unique Device Identifier(s)
ROB10000	CORI Starter Kit	00885556755068
ROB10024	Real Intelligence CORI	00885556757420
ROB10197	CORI STARTER KIT - UNIVERSAL	00885556796849

Dear Customer:

This letter is to inform you that Blue Belt Technologies, Inc., a wholly owned subsidiary of Smith & Nephew, Inc., collectively referred to herein as Smith+Nephew, has initiated a field action to voluntarily correct the CORI◇ Surgical System with Real Intelligence Software due to increased Marker Registration Error (MRE) which may cause tracker arrays to flicker on screen of the CORI Surgical System during use.

This field action has been reported to the relevant competent authorities.

Patient Impact

Smith+ Nephew recommends that physicians maintain their routine patient follow-up protocol.

Risks to Health	In the most likely scenario, the user adjusts the camera position and/or uses a backup device to continue use of the CORI Surgical System. This causes minimal to no delay. There is no hazardous situation and no harm. In the worst-case scenario, there is a surgical delay of greater than 30 minutes. To date, Smith+Nephew is not aware of any cases where surgical delay may have resulted in surgical complications. In the event that the flickering occurs doing bone removal, the bur will retract or stop spinning. However, a bone gouge can occur if the surgeon is moving faster than the recommended cutting velocity (30mm/sec) as indicated by the yellow drill symbol on the screen and described in the User Manual Warnings. The

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	gouge in the cut surface can be filled with cement and does not negatively affect implant fixation.
Actions to be taken by the user	1. Ensure that the contents of this Field Safety Notice are read and understood by those within your organisation who may use Real Intelligence CORI. 2. Please see attached IFU Addendum for troubleshooting tips and notes to enhance the consistency of visibility of the markers and tracking arrays. This IFU Addendum can be found at https://ifu.smith-nephew.com/ by searching IFU number 1000264245. 3. Please complete the Customer Response form and email or fax it to your national Smith+Nephew agency/distributor. 4. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. 5. A Smith & Nephew Robotics Representative will be deployed to your site to implement a new software version once it is available.

If you or any of the healthcare providers you serve have any questions regarding this information, please contact your national Smith+Nephew agency/distributor.

Smith+Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.

Thank you for your attention and cooperation.

Appendix 1: IFU Addendum

Customer Response Form

Please read in conjunction with the Field Safety Notice and return the completed and signed Customer Response Form by <date>.

Reference: C-2024-03
Concerned Devices: Real Intelligence CORI

1. Correction Acknowledgement details	
Email	<Local market to add>
Customer Helpline	<Local market to add>
Fax	<Local market to add>

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

2. Customer Details			
Healthcare Organisation / Facility Name*	<Fillable form field>		
Name of **all** Facilities/Hospitals covered by this response*	<Fillable form field>		
Facility / Hospital Address*	<Fillable form field>		
Telephone Number	<Fillable form field>	Email address	<Fillable form field>
Name of your supplier / wholesaler (if not Smith+Nephew)	<Fillable form field>		
Healthcare Organisation / Facility Stamp (if available)	<Fillable form field>		

3. Customer action undertaken on behalf of Healthcare Organisation / Facility Please complete/tick as appropriate.		
☐ Yes	I confirm receipt of the Field Safety Notice and that I read and understood its content.*	
☐ Yes ☐ No	Has your Healthcare Organisation / Facility distributed the product to other organisations? If you have answered yes, tick all that apply: *	
	☐ I have identified customers that received or may have received this device.	
	☐ I have informed the identified customers of this FSN.	
	☐ I have received confirmation of reply from all identified customers.	
☐ Yes	I performed all actions requested by the FSN. *	
Tick Appropriate Response:*	☐ Yes	Neither I nor any of my customers has any affected devices in inventory.
	☐ Yes	In our Organisation / Facility we have concerned devices. Complete **Section 4** with material and serial number related to devices to be corrected. Serial numbers can be found on the back of the console. 

4. Devices to be Corrected	
Material Number	Serial Number

Print Name*	<Fillable form field>		
Signature*	<Fillable form field>	Date*	<Fillable form field>

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.