FSN Ref: 2025-FA-001

Date: 29/07/2025

# Urgent Field Safety Notice
# Versius Surgeon Console

Dear Customer,

CMR Surgical Ltd have become aware of a potential issue with certain serial numbers of the Versius Surgeon Console. There is a possibility that the energy button on the left-hand controller may remain activated after the surgeon has released the energy button, which could cause the electrosurgery function to remain engaged. The failures that have occurred in the field all occurred within the first 3 surgeries requiring electrosurgery.

The continued use of the device is considered appropriate based on an internal review taking into account the benefit provided to patients compared to any potential risk that may be posed.

CMR Surgical Ltd regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

If you have any questions regarding this communication, please contact a local CMR Representative.

| **1. Information on affected device** | |
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| **1.1** | **Device type:** |
| | The Versius Surgeon Console is part of the Versius Surgical System and is used by the surgeon to control the surgical instruments and endoscope when performing minimal access surgery. The surgeon console includes a surgeon display and two (left and right) hand controllers. |
| **1.2** | **Commercial name:** |
| | Versius Surgeon Console |
| **1.3** | **Unique Device Identifier(s) (UDI-DI):** |
| | (01)05060548210045 |
| **1.4** | **Intended purpose:** |
| | The Versius Surgeon Console provides the main interface for the surgeon to control the movements and use of robotic arms with the help of two hand controllers and three-dimensional endoscopic visualisation through 3D glasses. |
| **1.5** | **Device model/catalogue/part number(s):** |
| | V-SS-1000 |
| **1.6** | **Affected serial or lot number range:** |
| | 30715, 60290, 60293, 60294, 60296, 60297, 60299, 60300, 60301, 60303, 60306, 60307, 60308, 60310, 60311, 60312, 60314, 60317, 60318, 60319. |

| **2. Reason for Field Safety Corrective Action (FSCA)** | |
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| **2.1** | **Description of the product issue:** |

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|---|---|
| | The energy button on the left-hand controller may remain activated after the surgeon has released the energy button, which could cause the electrosurgery function to remain engaged. |
| **2.2** | **Hazard giving rise to the FSCA:** |
| | The potential hazardous situation for the patient, as a result of this issue, is unintentional exposure to electrosurgery. If electrosurgery is unintentionally active, it has the potential to lead to laceration or perforation of organs, blood vessels or local nerves. This will depend on the anatomic location involved in the procedure.<br><br>To date there has been no harm to any patient.<br><br>This Field Safety Notice has no impact on patients who have already undergone a procedure using the Versius Surgeon Console.<br><br>There is no risk to the user. |
| **2.5** | **Background on issue:** |
| | CMR Surgical Ltd was made aware of five instances in the field where electrosurgery remained active following the release of the energy button by the surgeon. These instances occurred within the first ten surgeries carried out with the respective device. No harm to the patient or user occurred as a result of these incidents.<br><br>Following an investigation, the root cause of the potential issue has been traced back to a specific batch of circuit boards within the hand controller. The batch exhibits higher dimensional variation resulting in mechanical interference between the button and the housing. This interference can result in the button becoming stuck down when pressed.<br><br>The batch of circuit boards affects a small number of Versius Surgeon Consoles in the field, and we have traced all relevant serial numbers. |

| **3. Type of action to mitigate the risk** | | |
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| **3.1** | **Action(s) to be taken by the user:** | |
| | ☒ Identify device | ☒ Quarantine device (Serial number dependent) |
| | ☐ Return device | ☐ Destroy device |
| | ☐ On-site device modification/inspection | ☐ Follow patient management recommendations |
| | ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) | ☐ None |
| | ☒ Other:<br><br>Actions required are dependent on the number of surgeries that have been carried out for each device. For units that have performed less than 50 surgeries the unit will be immediately quarantined and withdrawn from use until the controller is replaced. Units that are in the field and that have performed 50 or more surgeries will have the controller replaced within this FSCA, | |

but it is not proposed that withdrawing these units from use due to the low risk of the issue occurring:

| Serial Number | Country | No Of Surgeries (as off 04/08/2025) | Action |
|---|---|---|---|
| 60290 | India | 0 | Quarantined and withdrawn from use until the controller is replaced |
| 60308 | France | 0 | Quarantined and withdrawn from use until the controller is replaced |
| 60310 | El Salvador | 0 | Quarantined and withdrawn from use until the controller is replaced |
| 60314 | France | 0 | Quarantined and withdrawn from use until the controller is replaced |
| 60318 | India | 0 | Quarantined and withdrawn from use until the controller is replaced |
| 60319 | Romania | 0 | Quarantined and withdrawn from use until the controller is replaced |
| 60307 | France | 4 | Quarantined and withdrawn from use until the controller is replaced |
| 60299 | France | 11 | Quarantined and withdrawn from use until the controller is replaced |
| 60312 | UK | 12 | Quarantined and withdrawn from use until the controller is replaced |
| 60311 | UK | 19 | Quarantined and withdrawn from use until the controller is replaced |
| 60317 | Romania | 20 | Quarantined and withdrawn from use until the controller is replaced |
| 60297 | Bulgaria | 29 | Quarantined and withdrawn from use until the controller is replaced |
| 60293 | France | 31 | Quarantined and withdrawn from use until the controller is replaced |
| 60306 | El Salvador | 63 | Continue to use, follow actions below if issue occurs. Controller will be replaced before 30 September 2025 |
| 60303 | Poland | 84 | Continue to use, follow actions below if issue occurs. Controller will be replaced before 30 September 2025 |
| 60296 | Germany | 105 | Continue to use, follow actions below if issue occurs. Controller will be replaced before 30 September 2025 |
| 60300 | Italy | 124 | Continue to use, follow actions below if issue occurs. Controller will be replaced before 30 September 2025 |
| 30715 | UK | 125 | Continue to use, follow actions below if issue occurs. Controller will be replaced before 30 September 2025 |
| 60301 | UK | 141 | Continue to use, follow actions below if issue occurs. Controller will be replaced before 30 September 2025 |
| 60294 | Poland | 180 | Continue to use, follow actions below if issue occurs. Controller will be replaced before 30 September 2025 |

Any users of the potentially affected Versius Surgeon Consoles, that are not required to be quarantined due to low risk, to be informed of the issue and how to address it if a problem arises as follows:

| | | |
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| | *In case of malfunction where electrosurgery remains active following release of the energy button: Immediately press the clutch button to stop energy activation. While disengaged, press the energy button to ensure normal function is regained before re-engaging.*<br>*If normal function is not regained stop using the console and inform CMR Surgical Ltd.* | |
| **3.3** | **Is customer reply required?** | Yes |
| **3.4** | **Action(s) being taken by the manufacturer:**<br>☐ Product removal ☒ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br>CMR Surgical Ltd, or its local distributor, will pro-actively carry out field replacements of the affected part on all the Versius Surgeon Consoles with serial numbers listed in section 1.6 of this Field Safety Notice. | |
| **3.5** | **By when should the action be completed?** | 30 September 2025 |

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| **4.** | **General Information** | |
| **4. 1** | **Field Safety Notice Type** | New |
| **4.2** | **Further advice or information already expected in follow-up Field Safety Notice?** | No |
| **4.3** | **Manufacturer information** | |
| | **Company name** | CMR Surgical Ltd |
| | **Address** | CMR Surgical Ltd<br>1 Evolution Business Park<br>Milton Road<br>Cambridge<br>CB24 9NG |
| | **Website address** | cmrsurgical.com |

## 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 transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

If you experience any issues, please report as a complaint as per your normal process.

Complete and return the Customer Response Form acknowledging this Field Safety Notice.

Please be informed that the appropriate Regulatory Authority for your region has been notified of this Field Safety Notice.

**Contact reference person:**

Debbie Gallagher
Post-Market Surveillance Manager
CMR Surgical Ltd
field.actions@cmrsurgical.com

*Signature*

*Date*

08 August 2025