Medtronic

URGENT FIELD SAFETY NOTICE

Hugo™ RAS System, Bipolar Instrument Failure

Customer Notification

Affected Model Numbers: Product	CFN	GTIN
Bipolar Fenestrated Graspers	MRASI0004	10884521739970 10884521826700 10884521844582
Bipolar Maryland Forceps	MRASI0005	10884521739987 10884521826717 10884521844599

See Appendix A for specific Serial Numbers impacted

February 2026

Medtronic Reference: FA1537
EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Healthcare Professional/Risk Manager:
The purpose of this letter is to advise you that Medtronic is initiating an urgent field safety notice for specific serial numbers of the Bipolar Wristed Instruments for the Hugo™ robotic-assisted surgery (RAS) system. The instruments in scope were manufactured between November 2022 and November 2025 and have been identified as susceptible to exhibiting an elevated rate of failure, which may lead to patient injury if it were to occur.

Issue description:
Hugo™ robotic-assisted surgery (RAS) system Bipolar Fenestrated Graspers and Bipolar Maryland Forceps, Customer Facing Numbers MRASI0004 and MRASI0005 respectively, have been identified to have an increased likelihood of component failure within the instrument's drive cable pulley assembly due to manufacturing variations. When this failure occurs, the instrument jaw's actuation and articulation will be incorrect, uncontrolled motion may occur, and a visible small white plastic portion of the instrument's pulley component may become disengaged and loose within the patient's cavity. The Hugo™ RAS System will detect this failure and halt telerobotic control of the affected instrument.

Risk to health:
Between February 2023 and January 2026, Medtronic has been informed of the bipolar instrument failure associated with this field safety notice occurring in 0.7% of surgical procedures, with a recent elevated rate of failure observed which has since stabilized. There have been fourteen (14) reported cases with twenty-one (21) observed harms to the patient, with five (5) cases leading to serious patient harm. Observed reported harms have

been Delay of Treatment (prolonged surgical procedure) greater than 30 minutes, Unretrieved Foreign Body in Patient, Radiation Exposure to locate disengaged components, and Tissue Damage/Trauma due to conversion to open surgery (conversion was associated with other complications in addition to the instrument's pulley). The potential for additional harm includes, but is not limited to, bleeding, bowel perforation, carcinogen exposure, foreign body reaction, and inflammation.

The continued use of Hugo™ Bipolar Instruments has been determined to be appropriate based on an internal review, with consultation of independent panel of surgeons, considering the benefit of patients access to minimally invasive robotic surgery potential risk that may be posed by this failure.

This field safety notice does not have an impact on patients who have previously undergone a procedure using the Hugo™ RAS system without a related complication. These patients should continue to be monitored per your practice's normal follow-up procedures.

Mitigating information for clinicians:

- Prior to use of the Bipolar Fenestrated Graspers or Bipolar Maryland Forceps instruments, inspect them to ensure they are not damaged and the instrument jaws are aligned with each other. If damage is observed, do not continue using the instrument.
- Upon use of the Bipolar Fenestrated Graspers or Bipolar Maryland Forceps instruments, check for correct motion and if incorrect or uncommanded motion is observed at any time during the procedure, immediately cease use of the instrument.
- If the white plastic portion of the instrument's pulley component is observed or suspected of being disconnected or separated, the loose white plastic should be immediately secured and removed from the patient cavity prior to taking further action.
- The white plastic which may become dislodged is not radio-opaque. As a result, if the white plastic becomes disengaged, it will not be directly visible under radiography. Radiation based imaging is not advised for locating the white plastic and may lead to unnecessary radiation exposure.
- Upon instrument failure, removal of the instrument must be done following the Disabled Instrument Workflow, ensuring that the instrument is visualized at all times. Instruction for this workflow are within the Hugo RAS User Guide and/or Hugo Quick Reference Guide.

Actions being taken by Medtronic:

- Medtronic is implementing manufacturing improvements to further control the manufacturing process and reduce the risk of this device failure. Bipolar Instruments built using the improved process are expected to become available within the coming months.

Actions to be taken by customers:

- Immediately notify all personnel in all care environments in which the Hugo ™ RAS system is used about this Field Safety Notice.
- The continued use of Hugo™ Bipolar Instruments has been determined to be appropriate based on an internal review, with consultation of independent panel of surgeons, considering the benefit of patients access to minimally invasive robotic surgery potential risk that may be posed by this failure. This assessment

may be augmented in individual surgeries by determining any circumstances that materially change the benefit or risk.

- If you experience a Bipolar Instrument failure as described in the above issue description, or have identified damage or jaw misalignment prior to use, replace the instrument and report any incidents related to this issue to your local Medtronic representative.
- If you are aware of any incidents related to this issue, please contact your local Medtronic representative to provide information regarding those events.
- Please maintain a copy of this notice in your records.

Product Scope:

See Appendix A: List of Affected Serial Numbers.

Regulatory notification:

Medtronic has notified the Competent Authority of your country of this issue.

We 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 Medtronic Representative.

Sincerely,

Local / BU Manager

Enclosure:

- List of Affected Serial Numbers

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Appendix A: List of Affected Serial Numbers

The table below is to be applied only for Bipolar Fenestrated Graspers (MRASI0004) and Bipolar Maryland Forceps (MRASI0005). Products of other types will have serial numbers within this scope, these are unaffected. Please refer to the specific product name and CFN when applying this table.

<table>
<tr><th rowspan="2">Product Name</th><th rowspan="2">CFN</th><th rowspan="2">GTIN</th><th colspan="3">Serial Numbers</th></tr>
<tr><th>Year (First 3 Digits)</th><th>ID (Second 3 Digits)</th><th>Range (Last 4 Digits)</th></tr>
<tr><td rowspan="6">Bipolar Fenestrated Graspers

Bipolar Maryland Forceps</td><td rowspan="6">MRASI0004

MRASI0005</td><td rowspan="6">10884521739970
10884521826700
10884521844582

10884521739987
10884521826717
10884521844599</td><td rowspan="2">C22</td><td>BAL</td><td>105 - 288</td></tr>
<tr><td>BAM</td><td rowspan="4">All serial numbers are impacted</td></tr>
<tr><td>C23</td><td rowspan="2">All serial numbers are impacted</td></tr>
<tr><td>C24</td></tr>
<tr><td rowspan="2">C25</td><td>BAA through BAK</td></tr>
<tr><td>BAL</td><td>5003 - 5865</td></tr>
</table>