Medtronic

URGENT FIELD SAFETY NOTICE

Hugo™ Robotic-Assisted Surgery (RAS) Arm Cart Assembly

Model Number - MRASC0002

Follow-up Communication / Recall

March 2025

Medtronic reference: FA1477

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

Dear Healthcare Professional,

As a follow-up to the Urgent Field Safety Notice Medtronic issued on 27 January 2025, Medtronic is now issuing a recall for the specific serial numbers of the Arm Cart Assembly (ACA) and Full Arm Assembly used with the Hugo™ Robotic-Assisted Surgery (RAS) system. These units had previously been removed from service and quarantined by the prior Urgent Field Safety Notice, due to the potential for affected ACAs to separate and detach during use and cause serious physical injury or death.

Issue Description and Risk:

Medtronic received a complaint reporting that a portion of an ACA detached from the rest of the assembly during the procedure prior to docking. In this instance a surgical procedure delay occurred. We have identified an issue with a single batch of fasteners used during manufacturing that caused this detachment risk. The detaching portions of the ACAs are heavy. If they detach during use, they could fall on the patient or staff and cause serious physical injury or death. You are receiving this communication because you have had an impacted unit containing fasteners from this batch.

As of February 4th, 2025, in addition to the one (1) complaint of detachment Medtronic has received four (4) additional complaints of loose mechanical connections on the ACAs. Each of these ACAs also contained fasteners from the same single batch identified above, although these ACAs did not have components detach. The issues related to the ACAs in these 4 complaints were all detected prior to use in a surgical procedure and have been returned to Medtronic. No adverse events or health hazards were reported in these four (4) additional incidents.

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Product Scope:

Product Name	Product Number	GTIN	Serial Number
Hugo™ RAS Arm Cart Assembly	MRASC0002	10884521836242	C22TLA0306

Actions taken by Medtronic:

- Initial communication to impacted customers with instructions to discontinue use and quarantine impacted units.
- Medtronic has retrieved or confirmed quarantine of all affected units and installed a replacement as needed.
- Medtronic continues to urgently and actively investigate root cause and corrective actions.

Actions to be taken by customers:

- You may continue using other ACAs that do not have the serial numbers listed above.
- Please complete the attached Customer Acknowledgement Form.
- Please maintain a copy of this notice in your records.

The Competent Authority of your country has been notified of this action.

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,

Country/OU manager