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# URGENT FIELD SAFETY NOTICE

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

### Model Numbers - MRASC0002

Immediate Notification

January 2025

Medtronic reference: FA1477

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

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is voluntarily initiating an immediate action Medical Device Correction for specific serial numbers of the Arm Cart Assembly (ACA) used with the Hugo™ Robotic-Assisted Surgery (RAS) system, due to the potential for affected ACAs to separate and detach during use and cause serious physical injury or death.

**Medtronic is advising to immediately discontinue use of the serial numbers listed below.**

**Issue Description and Risk:**

Medtronic received one complaint reporting that a portion of an ACA detached from the rest of the assembly during the procedure prior to docking. Our investigation into this complaint is still ongoing; however, we have identified a potential contributing factor that could create a similar detachment risk for the specific ACA serial numbers listed below. The investigation thus far has identified a single batch of component used in the assembly of these units, and you are receiving this communication because you have one of these impacted ACA's. 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.

**Product Scope:**

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

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**Actions being taken by Medtronic:**

- Medtronic continues to urgently and actively investigate root cause.
- Medtronic will provide additional instructions for these impacted ACAs as we complete our investigation.
- Medtronic representation will contact you to return the affected ACA and install a replacement ACA.
- Medtronic is issuing and distributing a follow-up Field Safety Notice and a Customer Acknowledgement Form to all affected consignees.

**Actions to be taken by customers:**

- Immediately discontinue use of the ACAs with serial numbers listed in the Product Scope table above.
- Quarantine these ACAs within a secure location in the hospital. Follow your local hospital procedures for quarantine of product and print and affix Appendix A below to affected ACAs.
- Await further direction from Medtronic before taking any additional action with these ACAs.
- You may continue using other ACAs that do not have the serial numbers listed above.
- 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/BU manager

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# Appendix A

**Quarantine: Do Not Use**

**FA1477**

**Hugo™ Robotic-Assisted Surgery (RAS)**