Medtronic

Urgent Field Safety Notice

Hugo™ Robotic-Assisted Surgery (RAS) Bipolar Fenestrated Grasper

MRASI0004 Hugo™ RAS Bipolar Fenestrated Grasper

UDI: 0763000B00006367Z

Immediate Action - Recall

August 2022

Medtronic Reference: FA1269

Dear Risk Manager, Healthcare Professional, and OR Materials Manager:

The purpose of this letter is to advise you that Medtronic is conducting an Urgent Field Safety Notice for the Hugo™ RAS bipolar fenestrated grasper instrument used with the Hugo™ RAS system.

Issue Description:

This Urgent Field Safety Notice (Recall) is being initiated following our investigation of nine (9) reported complaints of a jaw breaking on the Hugo RAS bipolar fenestrated grasper during clinical use. The break has the potential to cause a piece of the instrument jaw to detach while inserted in the patient's cavity.

This field action affects only the part number listed above and the serial numbers listed in Attachment #1: List of Affected Serial Numbers.

Risk to Health:

There have been no patient injuries reported in any of the complaints associated with this field action. However, the potential for harm exists and includes, but is not limited to:

- Unintended sharp edges, burrs, or other traumatic edges coming in contact with internal patient tissue, resulting in:
  - Tissue damage / tissue trauma / bleeding
- Components or materials disengaging into the patient cavity, resulting in:
  - Delay of treatment / prolonged procedure
  - Foreign body reaction
  - Inflammation
  - Radiation exposure
  - Bowel perforation
  - Bleeding
  - Foreign body in patient

Medtronic

Actions to be taken by the customer:

- Notify all personnel in all care environments in which the Hugo RAS bipolar fenestrated graspers are used about this field action.
- Please immediately quarantine and discontinue the use of the affected item code with associated serial numbers listed in Attachment #1: List of Affected Serial Numbers.
- Please return the affected product as indicated below. All products from the affected item code and associated serial numbers must be returned.

Actions being taken by Medtronic:

- Medtronic Technical Support/Field Service/Sales representatives will assist customers with the return of affected product.

Additional Information:

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

We regret any difficulties this issue 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 your Medtronic representative at <XXXX>.

Sincerely,

Local / BU Manager

Enclosure: Attachment #1: List of Affected Serial Numbers.