

## Urgent Field Safety Notice

### TruClear™ Hysteroscopic Tissue Removal System Control Unit

#### Recall

Product Names	Global Trade Item Number (GTIN)	Customer Facing Number (CFN) / Model #	Serial Number
TruClear Hysteroscopic Tissue Removal System Control Unit	10884521749931	7209808	YF1142

May 2022

Medtronic reference: FA1259

Dear Healthcare Professionals,

The purpose of this letter is to advise you that Medtronic is undertaking a voluntary recall of the TruClear Hysteroscopic Tissue Removal System Control Unit related to electrical component failure within the control unit. The observed failure mode is a loss of function of the device when used with handpiece and foot switch. Medtronic has received 23 complaints related to this issue as of 18-MAY-2022.

The potential harm for this issue is incomplete treatment that may result in intraoperative delay while an alternative device is being located. In cases where alternatives are unavailable, the procedure may require cancelation. This may subject the patient to an additional procedure to conclude treatment, with its concomitant sedation or anesthesia. No serious patient injuries have been identified to date.

Note: This issue does not pose additional risk with other devices, such as the handpiece or foot switch, as the device will not operate if this error occurs; nor will the control unit recover functionality without repair.

#### Customer Instructions:

Medtronic records indicate that your facility has received one or more of the TruClear control units. As a result, Medtronic requests that you immediately take the following actions:

- Identify and quarantine all affected product.
- Return all affected product in your inventory to Medtronic.

- Your local Medtronic Representative can assist you as necessary in initiating the return of this product.
- If you have questions or concerns regarding this recall, please contact your Medtronic representative.

Medtronic will notify the Competent Authority of your country about this matter.

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 issue or communication, please contact your Medtronic Field Representative at [franck.forget@medtronic.com](mailto:franck.forget@medtronic.com)

Sincerely,

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