Medtronic

Urgent Field Safety Notice

IPC Powerease System Model Number 2300000

Powerease Driver Wobble Out of Box Failure

Recall

July 2025

Medtronic Reference: FA1504

EU Manufacturer Single Registration Number (SRN): US-MF-000023264

Dear Risk Manager/ Customer,

The purpose of this letter is to advise you that Medtronic is recalling specific serial numbers of the IPC Powerease System (Model Number: 2300000). This recall was initiated because of reports of out of box failure for device wobble.

Medtronic records indicate that your facility may have at least one of the impacted devices (see Attachment A: Product Serial Number List).

The IPC Powerease System is indicated for drilling, tapping, and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. The IPC Powerease System is also used in the placement of screws, or cutting of screws, posts, and rods.

Issue Description:

This recall was initiated due to the potential for out of box failures for device wobble which is due to misalignment between quick connect and shaft main driver components.

Potential Health Hazard:

Up until June 26, 2025, Medtronic has received 35 complaints of device wobble within the affected device population, indicating potential health hazards related to degraded or loss of device functionality in specific lots (see Attachment A). Although no patient injuries have been reported, some cases have experienced procedural delays due to this issue.

The use of drills exhibiting wobble or eccentricity, particularly if Instructions for Use (IFU) checks for wobble are not followed, could potentially result in excessive tissue and bone destruction, including the risk of nerve root or spinal cord injury.

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Customer Actions:

- Identify, segregate, and quarantine and stop use of any affected products within your inventory. The list of affected device serial numbers is included in Attachment A: Product Serial Number List.
- Your Medtronic field representative will coordinate the replacement of your affected product.
- Return affected product in your inventory to Medtronic.
- Please complete the enclosed Customer Acknowledgement Form and email to <XXXX>. This form must be returned even if you do not have any affected product in your possession.
- Please share this communication within your organization, with other organizations where impacted devices have been transferred, and any other associated organizations that may be impacted by this action.
- Please maintain a copy of this letter for your records.

Additional Information:

Medtronic has notified the Competent Authority of your country 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 your Medtronic Representative.

Local / OU manager

Enclosures:

- Attachment A: Product Serial Number List
- Customer Acknowledgement Form

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Attachment A

Product Serial Number List

IPC POWEREASE System, Powerease Driver

Model Number: 2300000

GTIN: 00613994448705							
PEU21299	PEU21300	PEU21301	PEU21302	PEU21305	PEU23015	PEU23016	PEU23017
PEU23121	PEU23124	PEU23125	PEU23170	PEU23175	PEU23176	PEU23177	PEU23178
PEU23179	PEU23180	PEU23181	PEU23182	PEU23183	PEU23235	PEU23314	PEU23316
PEU23317	PEU23318	PEU23319	PEU23320	PEU23322	PEU23323	PEU23324	PEU23325
PEU23326	PEU23327	PEU23328	PEU23329	PEU23330	PEU23331		