Medtronic

Urgent Field Safety Notice

Mazor X™ robotic guidance system

Model TPL0059, Software Version 4.2.2 or 5.0.1

System Software update to version 5.1.1

Service Notification

October 2023

Medtronic Reference: FA1350
EU Manufacturer Single Registration Number (SRN): IL-MF-000020000

Dear Healthcare Professional, Risk Manager,

The purpose of this letter is to inform you that Medtronic is conducting a software update to the Mazor X™ robotic guidance system model TPL0059 ("Mazor X™ systems"). The update is applicable to systems running version 4.2.2 or 5.0.1 of the system software and will update to version 5.1.1. The anticipated availability of this software is dependent upon regulatory approval or derogation in your country. Medtronic field service engineers will reach out to accounts to update all Mazor X™ systems from version 4.2.2 or 5.0.1 to version 5.1.1 once your country's regulatory body has provided the necessary approvals.

Issue Description:

Software update version 5.1.1 is a service pack that contains incremental software improvements and anomaly fixes. While the majority of the changes in version 5.1.1 represent enhancements to the software, four (4) updates included in this software update version are intended to correct four (4) anomalies present in prior software versions (5.0.1 and 4.2.2). While the potential for the four (4) issues to occur is unlikely, Medtronic is providing this notification to raise awareness of the anomalies, the potential patient risk and the planned updates. Please continue to use the Mazor X™ system as instructed in the instructions for use. Anomalies addressed with 5.1.1 are:

1. Unwanted arm movement anomaly while continuously pressing up/down with the mouse: Specifically, while continuing to press arm up/arm down with the mouse, the surgical arm movement does not immediately terminate once the press is released. Medtronic has received one (1) customer complaint regarding this issue which resulted in no patient harm other than a brief procedural delay.

2. Work Volume anomaly during prone procedure: The surgical arm has the potential to collide with the bone mount tools under certain conditions. This anomaly can occur while using the dual clamp to connect the patient, and the work volume camera does not capture the bone mount structure correctly. Medtronic has received seven (7) customer complaints regarding this issue, all complaints resulted in no patient harm other than a brief procedural delay.

3. Work Volume anomaly in lateral procedure with towers: The surgical arm has the potential to collide with a tower when moving under certain conditions. This anomaly can occur if the arm is sent to "snapshot" position while it is located at the base of the tower. Medtronic has not received any customer complaints regarding this issue.

Potential Health Hazard related to Anomalies #1-#3:

In addition to the patient harm of procedural delay there is potential of the procedure being completed without robotic guidance or an additional surgical procedure. The potential for patient injury due to surgical arm collision associated with the above anomalies is low due to the slow velocity of surgical arm movement and ability to stop any unintended movement via the emergency stop button.

4. S&P (Scan & Plan) workflow anomaly: During an S&P workflow the user is instructed to use intraoperative CT imaging when capturing the patient location for system accuracy. If the surgical system mount is unlocked in the second segment there is risk of shift of the system and/or the patient without detection. The system allows the operation to continue even if the patient is not re-registered. The user manual instructs the user to perform a new registration before continuing to operate. This anomaly can occur if the system instructions via software or labeling are not followed. Medtronic has received one (1) customer complaint that was reported that resulted in patient injury of the nerve root during the procedure due to screw misplacement with no patient symptoms reported post-operatively.

Potential Health Hazard related to Anomaly #4:

In addition to the reported patient injury there are additional potential patient harms that can occur if the above sequence of events occurs. There is potential of the misplaced hardware to cause nerve damage or great vessel injury which could lead to permanent neurological injury or death.

Customer Actions:

- Please continue to use the Mazor X™ system as instructed in the instructions for use.
- Please complete and return the customer confirmation form enclosed with this letter, acknowledging that you have received this information.

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- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Medtronic Actions:

Medtronic field service engineers will reach out to accounts to update all Mazor X™ systems from version 4.2.2 or 5.0.1 to version 5.1.1 once your country's regulatory body has provided the necessary approvals.

If you have questions regarding this update, you may contact your Medtronic Representative.

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 understanding. If you have any questions regarding this communication, please contact your Medtronic Sales Representative.

Sincerely,
Medtronic GmbH