Medtronic (Schweiz) AG
Talstrasse 9
3053 Münchenbuchsee
www.medtronic.com

Tel. 031 868 01 00
Fax 031 868 01 99
E-Mail swisscontact@medtronic.com

URGENT FIELD SAFETY NOTICE

O-arm™ O2 Imaging System (O2)

Service notification

July 2023

Medtronic Reference: FA1351
Single Registration Number, SRN: US-MF-000023106

Dear Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is issuing a voluntary Correction for the O-arm™ O2 Imaging System (O2) serial numbers listed below.

Issue Description:
Medtronic has identified through internal manufacturing record review that your system may have an internal ground cable that was installed incorrectly. This issue with the ground cable does **not** impact the functionality, performance, or safety of the system. However, if the cable was installed incorrectly, it may present a hazard to Medtronic engineers when servicing the system due to potential of electric shock.

Risk to patient, operator or service personnel:
Medtronic has received zero (0) complaints associated with this issue. The impacted cable is located inside of the O-arm system and is not accessible to customers. There is no risk to patients or operators. This nonconformance does not have any impact on the functionality of the system. However, when the cable is installed inverted, there is a potential safety risk for any personnel attempting to service the O-arm or accessing the area where the cable is encased and stored. Medtronic is the Sole Source Service provider for the O2. Accordingly, only Medtronic authorized, and trained personnel should be servicing or repairing the O2.

Additionally, this notification has no impact on patients who have previously undergone a procedure using the O-arm™ O2 Imaging System (O2). These patients should continue to be monitored per your practice's normal follow-up procedures.

Actions for Customer:
- Please continue to use the device as per your facility protocol. There is no risk to patient or other users when the system panels remain on the system.
- Immediately notify all personnel in all care environments in which the O-arm™ O2 Imaging System (O2) is used about this Medical Device Correction notice.
- Please post this notification in a prominent location and maintain awareness of this matter until the issue is resolved by your Medtronic Field Service Engineer.
- 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.
- Complete and return the customer confirmation form.

Actions for Medtronic:

- Medtronic will contact customers to schedule servicing of your O-arm™ O2 Imaging System (O2) to correct this issue. In the interim, if you have questions regarding this issue, contact your Medtronic representative / Technical Services
- Medtronic is the Sole Source provider for the O2. Accordingly, only Medtronic authorized, and trained personnel should be servicing or repairing the O2.

Product Scope:

Product Name	Model#	GTIN/Material #	Serial #
Système d'imagerie O-arm™ O2	BASE SYS BI70002000 O-ARM SYS O2	00763000616434	C3290

Additional Information:

Medtronic has notified Swissmedic 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.

Sincerely,
Medtronic (Schweiz) AG