Follow Instructions for Safe Use of Electrical Operating Room Tables - Letter to Health Care Providers

February 29, 2024

The U.S. Food and Drug Administration (FDA) is raising awareness among health care providers and facilities about the safe use of electrical operating room tables. The FDA has received reports of adverse events associated with electrical operating room tables and is providing recommendations for health care providers to help protect patients.

Following the instructions provided in the manufacturer's product manual and user training can reduce potential risks associated with electrical operating room tables.

Recommendations for Health Care Providers and Facilities

- Review and follow the manufacturer's instructions for use - for each electrical operating room table being used.
- Ensure that training is provided for staff.
- Check for obstructions before repositioning the electrical operating room table.
    - If an obstruction is encountered during positioning of the operating room table, return the table to a neutral position, and remove the obstruction before attempting repositioning.
- Ensure that manufacturer recommended maintenance intervals and safety checks are followed.
- Do not exceed the maximum load limit indicated by the manufacturer.
- Report any problems with any operating room tables to the FDA.

Background

Operating room tables are used during surgical procedures to properly position a person in surgery. The tables have the ability to move and rotate for better positioning.

The FDA has received reports of adverse events associated with electrical operating room tables, including problems with positioning or unintended movement of the table which may result in serious patient injury, or extended or delayed surgical procedures which can lead to potentially

life-threatening complications. While the FDA believes that serious adverse events associated with electrical operating room tables are rare, health care providers and users should be aware that these can and do occur.

Although medical device reports (MDRs) are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources.

FDA Actions

The FDA will continue to work with manufacturers, health care organizations, and professional societies to encourage training and awareness of potential risks with the use of these devices.

The FDA routinely monitors postmarket performance of marketed devices. We will continue to collect and analyze all available information related to operating room tables to better understand the potential risks.

The FDA will keep health care providers and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with any operating room tables.

- You can submit voluntary reports through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

By promptly reporting adverse events, you can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) (DICE).