

Stop Using Gowns, including Surgical Gowns, from Laws of Motion PPE - Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) is alerting health care facility risk managers, procurement staff, and health care providers that gowns sold as medical gowns, including surgical gowns, sold by Laws of Motion PPE (LawsOfMotionPPE.com) have potential quality issues that affect the level of fluid barrier protection. The FDA is recommending that gowns manufactured or sold by Laws of Motion PPE should not be used as personal protective equipment at this time while the FDA continues our investigation.

Recommendations

The FDA recommends health care facility risk managers, procurement staff, and health care providers:

- Stop using gowns, including surgical gowns, purchased from Laws of Motion PPE until further notice.
- Identify the supplier or manufacturer of the gowns in your inventory.
- Report any issues with the quality or performance of gowns, including surgical gowns, to the FDA. See “Reporting Problems to the FDA” below.

Background

The FDA has become aware that gowns, including surgical gowns, purchased from Laws of Motion PPE may not provide protection, including fluid barrier protection, at the level for which the gowns are labeled.

Personal protective equipment (PPE) refers to protective clothing, helmets, gloves, face shields, goggles, respirators, or other equipment designed to protect the wearer from injury or the spread of infection or illness. A surgical gown (/medical-devices/personal-protective-equipment-infection-control/medical-gowns) is a personal protective garment intended to be worn by health care personnel during surgical procedures to protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate matter.

FDA Actions

The FDA is alerting health care facility risk managers, procurement staff, and health care providers about serious concerns with the quality of gowns, including surgical gowns, from Laws of Motion PPE. The FDA is assessing the extent of the concerns and is working with Laws of

Motion PPE to understand and address the issue.

The FDA will continue to keep health care providers and the public informed as significant new information becomes available.

Reporting Problems to the FDA

The FDA encourages health care facility risk managers, procurement staff, and health care providers to report any adverse events or suspected adverse events experienced with the gowns, including surgical gowns.

- Voluntary reports can be submitted 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.

Prompt reporting of adverse events 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).

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