

FDA Bans Powdered Gloves/Amalgam Separator Update



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The [FDA](#) issued a final rule December 19, 2016 banning powdered medical gloves—specifically **powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove**. This rule became effective January 18, 2017.

This decision is based on mounting evidence that powdered gloves pose a serious health risk to patients. Risks include airway and wound inflammation, post-surgical adhesions, and allergic reactions. The ban effectively removes these products from the marketplace and instructs those using them to immediately cease.

“This ban is about protecting patients and health care professionals from a danger they might not even be aware of,” said Jeffrey Shuren, M.D., director of FDA’s Center for Devices and Radiological Health. “We take bans very seriously and only take this action when we feel it’s necessary to protect the public health.”¹

If you have any of the banned products in your office, discard them immediately.

Dental effluent guidelines - UPDATE

The Environmental Protection Agency’s final rule on dental effluent guidelines (amalgam separators, certain line cleaners) [was released December 15, 2016](#). However, as of January 2017 the rule has been suspended and is subject to further review.

Notwithstanding the updated information on this proposed regulation and its current withdrawal from the Federal Register, some states and localities have enacted effluent guidelines/rules that already require your compliance. By way of example, under Michigan Board of Dentistry Rules, R 338.11811 Amalgam separator; installation and operation; requirements. Rule 1811. (1): “On or before December 31, 2013, a dentist shall install, or shall have installed, an amalgam separator on each wastewater drain in his or her dental office that is used to discharge dental amalgam waste.”

Check your state and local regulations on this subject and ensure you are in compliance.

¹ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491466.htm>

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