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Reuse of Single-Use Medical Devices

DISINFECTION AND STERILIZATION GUIDELINE
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Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

WHAT TO KNOW

Reuse of Single-Use Medical Devices from the Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).

Reuse of Single-Use Medical Devices

The reuse of single-use medical devices began in the late 1970s. Before this time most devices were considered reusable. Reuse of single-use devices increased as a cost-saving measure. Approximately 20 to 30% of U.S. hospitals reported that they reuse at least one type of single-use device. Reuse of single-use devices involves regulatory, ethical, medical, legal and economic issues and has been extremely controversial for more than two decades.⁹⁹⁰ The U.S. public has expressed increasing concern regarding the risk of infection and injury when reusing medical devices intended and labeled for single use. Although some investigators have demonstrated it is safe to reuse disposable medical devices such as cardiac electrode catheters,⁹⁹¹⁻⁹⁹³ additional studies are needed to define the risks⁹⁹⁴ and document the benefits. In August 2000, FDA released a guidance document on single-use devices reprocessed by third parties or hospitals.⁹⁹⁵ In this guidance document, FDA states that hospitals or third-party reproprocessors will be considered "manufacturers" and regulated in the same manner. A reused single-use device will have to comply with the same regulatory requirements of the device when it was originally manufactured. This document presents FDA's intent to enforce premarket submission requirements within 6 months (February 2001) for class III devices (e.g., cardiovascular intra-aortic balloon pump, transluminal coronary angioplasty catheter); 12 months (August 2001) for class II devices (e.g., blood pressure cuff, bronchoscope biopsy forceps); and 18 months (February 2002) for class I devices (e.g., disposable medical scissors, ophthalmic knife). FDA uses two types of premarket requirements for nonexempt class I and II devices, a 510(k) submission that may have to show that the device is as safe and effective as the same device when new, and a premarket approval application. The 510(k) submission must provide scientific evidence that the device is safe and effective for its intended use. FDA allowed hospitals a year to comply with the nonpremarket requirements (registration and listing, reporting adverse events associated with medical devices, quality system regulations, and proper labeling). The options for hospitals are to stop reprocessing single-use devices, comply with the rule, or outsource to a third-party reproprocessor. FDA guidance document does not apply to permanently implantable pacemakers, hemodialyzers, opened but unused single-use devices, or healthcare settings other than acute-care hospitals. The reuse of single use medical devices continues to be an evolving area of regulations. For this reason, healthcare workers should refer to [FDA](#) for the latest guidance.⁹⁹⁶

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CONTENT SOURCE:
[National Center for Emerging and Zoonotic Infectious Diseases \(NCEZID\)](#)



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