

## An FDA Perspective on Medical Device Sterilization, Reprocessing, and Infection Control

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Infection control is a cornerstone of health care and the medical device industry. Multi-use devices are ubiquitous in patient-care settings and successful reprocessing of these devices is integral to their safe and effective use. Multi-use devices also help to ensure a robust device supply chain and ensure that patients and medical professionals have access to the devices needed for patient care.

The COVID-19 public health emergency highlighted the importance of device reprocessing and of infection control devices such as PPE. The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) continues to work with our stakeholders in health care, industry, academia, and the public to ensure that multi-use devices are safe and effective for both regular use and for emergency use during the public health emergency. We also provide resources, tools, and guidance for device reprocessing and encourage device developers to consider sterilization and reprocessing of their device early in the design process in order to develop an effective strategy for controlling device microbial quality and ensuring effective infection control practices for their device.

In this presentation, I will present examples that illustrate the importance of considering device sterility and reprocessing during the design process and discuss why FDA's technical, scientific, and regulatory guidance for device reprocessing should matter to device developers in academia and industry. I will also discuss some of our ongoing efforts to promote innovation in medical device sterilization. Finally, I will provide an overview of some of our tools and resources that may be helpful to those considering how to sterilize or reprocess their device and make a case for early interaction with FDA if you have device specific questions, particularly for devices with novel or innovative designs and materials such as biologically derived materials or additively manufactured devices.