# Medistri

Providing Sterilization & Laboratory Services for the world's most innovative healthcare companies.

### From the Blog

## **Medistri's Single Load Cycles**

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Selecting the appropriate sterilization approach begins with understanding how different products behave under exposure. A single load cycle is designed to sterilize products that share comparable material properties, packaging configurations, geometry, and sterilization requirements. By processing only compatible items, the cycle parameters such as EO concentration, temperature, humidity, exposure time, and aeration can be precisely controlled and documented. This creates a sterilization environment that is highly predictable, reproducible, and traceable.

#### Why Certain Products Require a Single Load

Single load cycles are particularly valuable when products are sensitive to specific exposure conditions or when their physical characteristics influence sterilant penetration. This may include:

- · Devices with narrow lumens
- · Components containing embedded electronics
- Packaging with limited gas permeability
- Polymer-based products sensitive to temperature and humidity.

In these situations, combining them with unrelated items could compromise sterilant penetration, lead to material degradation, or challenge documentation accuracy. A dedicated single load ensures that all products experience uniform exposure throughout the sterilization chamber.

#### **Validation and Documentation Clarity**

Because single loads involve a defined and consistent group of products, validation parameters can be focused on shared material behavior, packaging characteristics, and penetration response. This simplifies cycle qualification, supports accurate SAL measurement, and streamlines documentation for compliance with ISO 11135 and regulatory requirements from FDA, Swissmedic, and MDR.

#### **How Medistri Develops Dedicated Single Load Cycles**

At Medistri, the development of a single load cycle begins with analyzing product characteristics, material compatibility, packaging configuration, geometry, and sterilant behavior. Our sterilization specialists design, validate, and monitor tailored cycles using physical, chemical, and biological controls to confirm performance, ensure regulatory compliance, and maintain long-term reproducibility.

#### A Controlled Path to Compliance and Reliability

Single load cycles are not designed to outperform mixed loads, nor to replace them. They serve a distinct role: to provide a controlled, reproducible, and traceable process for products that require uniform exposure conditions. They support manufacturers in protecting product quality, ensuring regulatory compliance, and designing validation strategies aligned with the device's intended use, configuration, and classification.

To learn more about our single load sterilization approach, visit our website <u>here</u> or contact our team at <u>contact@medistri.com</u>.



#### Consistency as a Process Advantage

The greatest advantage of a single load cycle is the uniformity of processing conditions. When all items in the load respond similarly to the sterilant, the cycle can be calibrated with greater precision. This allows biological and chemical indicators to be placed more strategically, enhances data accuracy, and improves the interpretability of results. It also reduces product-to-product variability, making the process easier to monitor, replicate, and control over time.