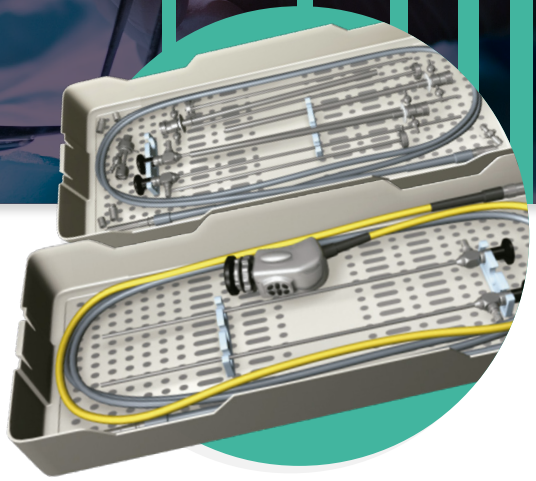
VOLUME 4

STERRAD™ SUPERIORITY

A FACTSHEET BY ASP™



The Importance of Instrument Validation

✓ Despite all efforts against healthcare-associated infections (HAIs), **22% of all surgical site infections (SSIs) are related to device reprocessing**;[1-5] a significant proportion is considered preventable[6]

✓ The Medical Device Manufacturer (MDM), the Sterilizer Manufacturer (SM) and health care professionals (HCPs) each play a critical role in device reprocessing to **prevent the incidence of an SSI**

✓ Instrument validation that demonstrates **effective sterilization of a particular medical device** is critical for sterility assurance and patient safety

Shared Responsibilities in Assuring Safe & Effective Sterilization

✓ Safety and quality standards for medical devices produced by the European Union require the MDM to **determine and communicate how each medical device should be reprocessed**[7]

✓ The MDM collaborates with the SM (e.g. ASP) to test the instrument's performance, in line with exacting standards,[8] providing **sterility assurance** and **ensuring material compatibility and functionality** (including device wear and material evolution after reprocessing)

✓ Following validation, the reprocessing method is approved by the MDM, who reflect this in its Instructions for Use (IFU)[8,9]

ASP plays a crucial role in ensuring effective sterilization and SSI prevention:

Functionality	Sterility	Processing
ISO 17664[9] / ISO 14937[8]	ISO 14397[8]	MDM IFU / ISO 17664[9] / ISO 14937[8]
The MDM produces a reliable medical device The MDM determines the functional compatibility and the methods of sterilization that can be approved for use	The SM provides a reliable sterilization method **ASP** evaluates the device for sterile efficacy with a specific STERRAD™ sterilization system	The HCP performs the sterilization process efficiently The HCP should follow the MDM's recommended IFU for sterilization

Effective sterilization and SSI prevention

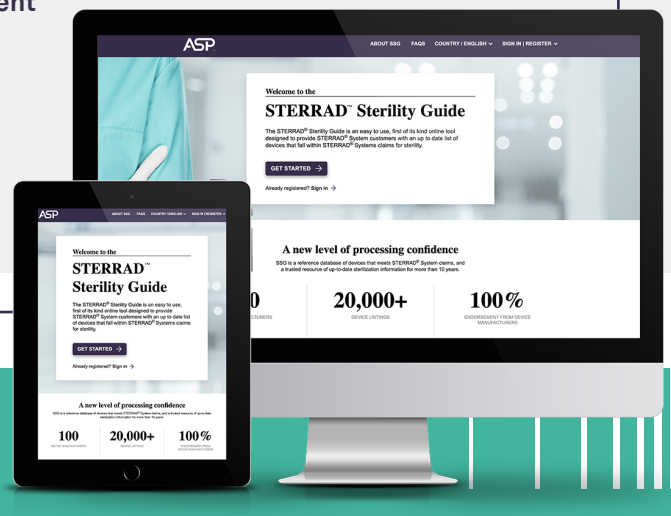
Similarity Does Not Equal Compatibility

- Each sterilizer, even if using the same sterilant, uses a **distinct combination of various parameters** to achieve sterility assurance (e.g. concentration, exposure time, temperature)
- This combination of parameters varies depending on the device(s) being reprocessed, and **must meet the claims' requirements of that cycle**
- Given this variation, without instrument validation in collaboration with the MDM, an SM **cannot assume sterility assurance** for a medical device; each medical device must be **thoroughly tested in line with exacting standards**[8] to ensure the highest level of patient safety

Assuming that sterilizers which use the same sterilant provide sterility assurance risks inadequate sterilization and, ultimately, may put patients at risk of harm.

The STERRAD™ Sterility Guide (SSG) Provides the Difference Between Assumed and Assured

- The SSG is a reference database of devices that meet STERRAD™ Systems sterility claims, with easy access to **more than 23,000 individually validated listings** from over 100 original manufacturers[10]
- ASP works directly with MDMs to perform **rigorous instrument validation**, accounting for potential real-world variables and **adhering to ISO 14937 exacting standards**[10]
- Upon successful validation, every listing is approved and endorsed by the original MDM, making the SSG a **trusted resource for up-to-date sterilization information**[10]



Key TAKEAWAYS

- Instrument validation in adherence with exacting standards, such as ISO 14937, is **vital for sterility assurance**
- Assuming sterility assurance based on similarities with sterilizers which use the same sterilant, rather than instrument validation, **risks inadequate sterilization** and may put patients at risk of harm
- The SSG is a trusted source of reprocessing information, with every listing having undergone rigorous validation, as well as approval by the original MDM, **providing the difference between assumed and assured sterility**

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