VOLUME 2

STERRAD™ SUPERIORITY

A FACTSHEET BY ASP™

Defining Chamber Capacity

Why is Capacity Important?

✓ The Central Sterile Services Department (CSSD) must **meet the demands of busy operating room schedules**, providing sterile surgical devices in line with rapid instrument turnover[1]

✓ The claims requirements of the sterilizer's manufacturer, and the configuration of chamber dimensions, **defines the type and number of instruments** which can be processed in each load and therefore impacts upon **device turnaround time and cycle efficiency**

How Can Capacity Impact Speed and Efficiency?

✓ The materials and complex design of advanced surgical instruments necessitates the use of low-temperature sterilization (LTS), to maintain device integrity[2]

✓ In a hospital setting, H_2O_2 sterilizers typically consist of two sizes:

- 30–50 litre: based in the department, serving its needs without requiring transportation to the CSSD
- 90–150 litre: based in the CSSD, serving the needs of the hospital

✓ Chambers with a capacity >150 litres **do not necessarily maximise benefit to the CSSD** given that:

- Surgical instruments requiring LTS comprise a smaller proportion of hospitals' inventories, relative to those compatible with steam sterilization.[3] Waiting for a sufficient volume of devices to complete the load could therefore create a **trade-off** between **fast turnaround times** from not delaying a partially full cycle, and running a full cycle to make **efficient use of sterilant and natural resources**
- The diversity of typical loads often requires that devices be split across different cycle types, driving down the volume of devices that need reprocessing in any single cycle

The need is clear: a balance between **usable capacity** and both **speed** and **efficiency**

Claims Requirements Determine Usable Capacity

✓ The **type and number of instruments which can be** reprocessed in any single cycle is determined by the claims requirements of the sterilizer's manufacturer[4]

✓ Claims requirements **do not relate to the physical size of the chamber** or the sterilant type; therefore systems of similar size or using the same sterilant **should not be assumed to possess the same compatibility**

The user is required by MDD/MDR to select one of the compatible methods, systems and cycles referenced in the Instructions for Use of the medical device manufacturer, following ISO standards (ISO17664).[4]

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For example, the STERRAD™ 100NX system is permitted to hold **40 lumens per load**,[5] while the STERIS V-PRO® maX system **can only hold 20**,[6] despite them being able to physically hold the same number of trays. While, both systems are permitted to hold two endoscopes[5,6]

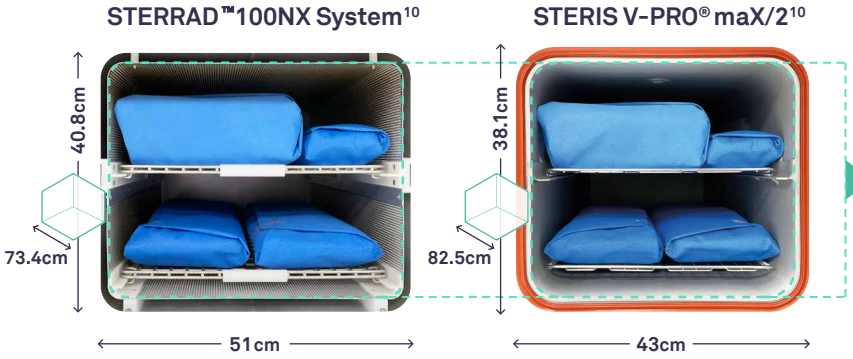
✓ As such, **claims requirements may limit the load capacity before filling the physical chamber**. This creates the potential for running partially full cycles, reducing the efficiency at which the cycle runs, and increasing the turnaround time in needing to complete multiple cycles; a system which supports a higher number of lumens per load, such as **STERRAD™ 100NX**, can reduce the likelihood of partially full cycles, potentially **increasing efficiency and reducing turna-round time**

Taking Dimensions into Consideration

- Secondary to claims requirements, chamber size may limit the type and number of trays that can be placed inside. However, rather than volume, the **configuration of chamber** dimensions determines usable capacity and therefore throughput

- Using different configurations of AESCULAP® containers, APTIMAX™ and PRO-LITE™[9] trays (Figure below), it was determined that standard kits for various surgical devices **fit equally** in both STERRAD™ 100NX and STERIS V-PRO® maX systems, and since trays cannot be piled up, there is **no difference in the number of trays each chamber can reprocess** (Figure)[7, 8]

- Despite their volumes, a wider chamber, such as that of the STERRAD™ 100NX allows **more convenient side by side reprocessing**,[7] minimizing the risk of trays touching each other and promoting **optimal H_2O_2 circulation** to facilitate effective sterilization (Figure)



Note: dimensions above represent the total size for both chambers.

Volume ≠ Capacity

The question raised: what is the true usable volume of each chamber?

Key TAKEAWAYS

A larger sterilization chamber does not always equate to more usable capacity

- The type and number of instruments which can be reprocessed in any single load is **constrained by claims requirements**, which must be carefully considered when determining the capability of LTS systems
- **Configuration of chamber dimensions** plays a critical role in determining usable sterilization capacity, and may have added benefits of ease of user access and promoting effective sterilization through optimal circulation
- Due to the smaller volume and diversity of surgical instruments requiring LTS compared to steam, a **larger sterilization chamber** may also force the user to **compromise either fast turnaround time or efficient use of sterilant** and natural resources

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