Efficiency in the CSSD

Advanced Sterilization Products

Addressing the unmet need for a rapid and cost-efficient sterilization process, whilst ensuring the highest level of patient safety

Efficiency in the Central Sterile Services Department (CSSD)

Inefficiencies in Medical Device Reprocessing Can Increase Costs and Resource Use Within the CSSD, and Impact Patient Care

The CSSD plays a critical role in ensuring patient safety by providing sterile devices for use in surgical procedures. The CSSD is also under constant pressure to improve turnaround time, reduce costs and optimise workflow efficiency, in order to maximise device availability for healthcare professionals and patients. Medical device reprocessing, therefore, has important cost and resource use implications within the CSSD, and can ultimately impact the efficiency of patient care for the hospital itself.

The cycle time of reprocessing modalities directly impacts the turnaround time of medical devices, while, the claims requirements of the manufacturer and configuration of chamber dimensions determines usable capacity; in turn, these factors influence the throughput of medical devices in the CSSD, and their availability for surgical procedures. To compensate for throughput inefficiency, and ensure that sterile devices are always available, hospitals might be required to hold larger inventories, incurring greater costs.[1]

Reprocessing modalities can also incur avoidable costs and resource use, driving inefficiency in the CSSD. These can arise as a result of device damage, which leads to increased device repair and replacement costs, or through excessive use of natural resources. Furthermore, some reprocessing modalities require compliance with strict regulations, due to their association with acute and long-term toxicities, in order to protect users, patients and the environment. Implementing the necessary protective measures can mitigate the risks associated with these modalities, however, can have the consequence of further driving inefficiency in the CSSD.

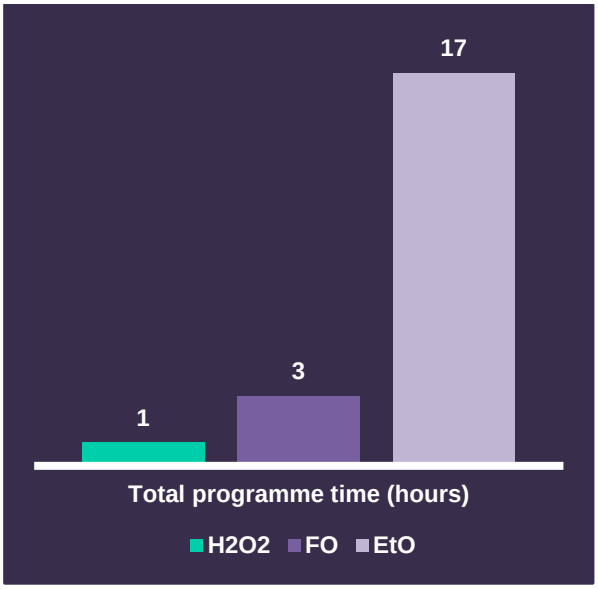
Medical device reprocessing can also impact the efficiency of patient care for the hospital itself, and result in cost burden sitting within other budgetary silos. If devices are not effectively sterilized, patients are put at risk of contracting healthcare-associated infections (HAIs), which are associated with significant morbidity, mortality and healthcare costs, leading to avoidable inefficiency in patient care.

As such, there is a need to take a holistic view of medical device reprocessing, to drive efficiency savings both in and outside of the CSSD.

Rapid Technologies May Reduce Inventory Burden to Help Meet Operating Room (OR) Demands

There is an increasing pressure from hospital ORs to maintain medical device availability for planned and unplanned procedures,[2] whilst ensuring the highest level of patient safety.

Aside from the safety concerns they raise, current reprocessing modalities, such as ethylene oxide (EtO) and formaldehyde (FO), are slow to turnaround instruments due to lengthy cycle times, driven by the need to aerate the load to remove toxic residues (Figure).[3] A long cycle time means that more devices must be held in inventory to ensure that sterile devices are always available, requiring greater capital investments.[1] Otherwise, lengthy turnaround times may delay operating schedules, reducing the throughput of patients and potentially compromising patient safety.[4]



With 22% of all SSIs being attributed to reprocessing procedures,[5-9] CSSD managers need rapid assurance of successful sterilization. However, conventional biological indicator (BI) readout times lengthen instrument turnover and may delay operating schedules due to unavailability of medical devices. To keep up with OR demands, CSSD staff may feel compelled to release devices without sterility assurance, potentially putting patients at risk of harm or delaying scheduled procedures.

Unavailability of surgical instruments is responsible for up to 40% of equipment-related incidents in the OR.[10]

Delaying a patient's surgery may increase morbidity and mortality.[4]

The claims requirements of sterilization systems' manufacturers, and the configuration of chamber dimensions, defines the type and number of instruments which can be processed in each load, impacting device turnaround time and cycle efficiency. Claims requirements may limit the load capacity before filling the physical chamber. As such, sterilizers with higher claims can contribute towards higher device throughput.

Upgrading to the latest reprocessing technologies could improve device turnaround time, meeting OR demand without requiring a large number of instrument sets to be held in hospitals inventories.

A Process that Limits Device Repair, Reduces Waste and Avoids the Need for Protective Measures May Promote Efficiency

Some reprocessing modalities hinder efficiency in the CSSD through avoidable cost and resource use, and can ultimately result in substantial economic burden.

Device damage

While heat- and moisture-labile devices are not suitable for steam sterilization, heat- and moisture-stable devices have been shown to be damaged by steam over time. Micro-surgical scissors have been demonstrated to exhibit signs of corrosion of the stainless steel cutting surface, suggesting severe oxidation, after 30 cycles of steam sterilization.[11] High wear rates could lead to more frequent repair and replacement costs.

In one US hospital, steam sterilization resulted in

34 battery replacements over a 6-month period at a cost of more than $8,500.

In addition, damaged surfaces act as hot spots for biofilm formation, which can lead to HAI outbreaks and risk harming patients.[12]

Excessive use of natural resources

Some reprocessing modalities, such as steam, EtO and FO are associated with high water and electricity consumption, incurring substantial costs.[13, 14]

A US hospital revealed that EtO sterilization formed 6% of the total water usage;

15 million litres anually.[14]

Eliminating EtO would save $9,000 annually through reductions in water and electricity consumption.

Protective measures

EtO, FO and H_2O_2 are linked with toxicities[15-17] and EtO and FO are considered carcinogenic.[18, 19] The CSSD must comply with strict regulations regarding their use.[20-24]

For EtO and FO, air monitors, ventilation and abatement systems and specialised storage facilities may all be required, and staff must undergo extensive training and regular health checks, incurring significant costs.[25] Sterilization with H_2O_2 does not typically require aeration of the load before handling, however, STERIS V-PRO® sterilizers have been shown to produce peak H_2O_2 emissions above that deemed safe by the American Conference of Governmental Industrial Hygienists (ACGIH®),[26] contributing to a hazardous working environment. Measures for mitigating these risks may drive inefficiency in the CSSD.

Devices reprocessed using high-level disinfection or liquid sterilization that are not used within a short time period must be reprocessed, wasting money and time, and requiring larger inventories to ensure availability.

A Reprocessing Modality which Avoids Inefficiencies in Patient Care By Helping to Prevent HAIs

HAIs are associated with significant morbidity, mortality and healthcare costs,[27] leading to avoidable inefficiency in the delivery of care. In Europe, the average prevalence of HAIs is 7.1%, with more than 4 million patients affected by HAIs every year,[27] costing approximately €7 billion.[28]

Annually, in Europe, HAIs cause

16 million extra days of hospitalisation,

37,000 attributable deaths

and contribute to

110,000 further deaths[27]

HAIs are associated with increased length of hospital stay (LOS), increase the risk of hospital readmission and represent a significant financial burden for health systems.[28, 29]

LOS in patients experiencing a HAI is

~3x higher

compared to those who do not (22 days versus 7 days, respectively; $p<0.001$).[30]

However, given the acknowledged reporting gaps in existing surveillance systems and data gaps, the scale of the burden arising from HAIs is considered to be greatly underestimated.[31]

Despite the existence of reprocessing guidelines and advances in device reprocessing methods, 22% of surgical site infections (SSIs) are related to equipment reprocessing.[5-9] A significant proportion of these HAIs is considered preventable.[32]

Sterilization offers the greatest margin of safety to device reprocessing, yet conventional high-temperature methods are not suitable for all devices. In fact, devices damaged by steam sterilization may promote biofilm formation and increase the risk of HAIs.[12] Many modern-day devices cannot tolerate high temperature steam sterilizers and require low-temperature sterilization (LTS) modalities. LTS modalities have the potential to offer certain advantages, however, EtO and FO are associated with a number of major drawbacks which themselves drive inefficiency in the CSSD.

There is an unmet need for a LTS modality that can sterilize medical devices in a timely and efficient manner without compromising the safety of CSSD personnel, operators of the medical device or patients.

The ASP Ecosystem

STERRAD™ 100NX / NX™ with ALLClear™ Technology
is a solution that provides integrated quality control features to minimise workflow disruptions

STERRAD VELOCITY™
is a fully integrated biological indicator that provides sterility assurance within 30 minutes

ASP ACCESS™
is a smart information-sharing technology that provides unique insight by allowing users to access sterilization information in real time

The ASP™ Ecosystem comprises innovative technologies to enhance device reprocessing. ASP ACCESS™ technology enables automated reconciliation of STERRAD VELOCITY™ BI results and cycles processed in STERRAD™ Systems with ALLClear™ Technology, and communicates results between connected devices. STERRAD™ Systems utilise a combination of H_2O_2 and low-temperature gas plasma to rapidly and safely sterilize medical devices and materials without leaving toxic residues.

Key features of the ASP™ Ecosystem ensureoptimal workflow efficiency and effectiveness, ultimately enhancing the quality of patient care.

Releasing Devices in a Timely Manner

STERRAD™ Systems enable fast instrument turnover, as they do not require lengthy aeration, offer a rapid sterilization cycle (24–60 minutes) and allow users to load and unload the chamber in a hands-free manner, saving time and increasing efficiency. This means that instruments can be re-used much sooner, avoiding delays to OR schedules.

In addition, STERRAD™ Systems with ALLClear™ Technology and ASP ACCESS™ improve workflow efficiency and in turn potentially help to minimise the risk of HAIs, through:

> **Connectivity and automaticity:** users are granted remote access of real-time sterilization records. Alerts to critical system information allow CSSDs to act quickly and prevent delays.

> **Reduced risk of human error:** automatic reconciliation of sterilization data reduces the risk of manual data collection errors, allows retrieval of sterilization data in case of infection and maintains audit-ready data.

> **Reduced delays:** STERRAD™ Systems with ALLClear™ Technology allow uninterrupted sterilizer operation by correcting issues that could cause cancellations, therefore minimising OR delays.

STERRAD VELOCITY™ assures sterility of devices within 30 minutes, allowing CSSD managers to optimise patient safety whilst keeping up with hospital demands.

> The reduced wait time (~30 mins) for sterility assurance may increase device availability; in turn OR delays[33] and patient burden may be minimised.[4]

> On-screen step-by-step instructions help to reduce the incidence of user error and optimise patient safety.

> A rapid BI provides sterility assurance that can be helpful in defending against potential legal challenges following HAIs without delaying workflows.

The rapid cycle time, automaticity and traceability offered by the ASP™ Ecosystem improves workflow efficiency, minimises human error risk, enhances compliance and can help reduce delays.

Reducing Device and Device Repair Expenditure

Sterilization by STERRAD™ Systems alleviates overall device-related economic burden by minimising device repair/replacement and maximising device turnover, allowing CSSDs to confidently hold a smaller device inventory and save device purchasing costs.

In one US hospital, the STERRAD™ System resulted in only 2 battery replacements in a 9-month period compared to 34 replacements in the previous 6 months when steam sterilization was used.[34] The estimated annual saving was $17,000.[34]

STERRAD™ Systems have been shown to result in:

58% risk reduction of instrument damage[35]

33% risk reduction in instrument repair costs[36]

50% reduction in instrument replacement rate[37]

Steam sterilization has also been shown to damage rigid scopes, such as arthroscopes, and delicate steel surgical equipment, particularly microsurgical scissors. The Orthopaedics and Urology departments of Barmherzige Brueder Hospital found that sterilizing rigid scopes with STERRAD™ Systems instead of steam reduced their average repair costs by 33%.[37]

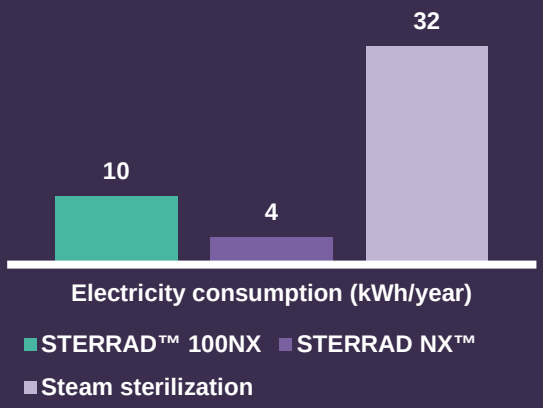
Increased H_2O_2 sterilization costs are offset by cost savings associated with less frequent instrument repairs. One Norwegian hospital found that switching from steam to H_2O_2 sterilization saved $84,000 in a single year.[35]

In addition, STERRAD™ Systems reprocess devices 21 times faster than sterilization with EtO. The increased rate of instrument turnover allows devices to be reprocessed for safe re-use much faster than EtO, reducing the demand for large and costly device inventories.

Reducing Resource Use

Compared to steam, EtO and FO sterilization, the ASP Ecosystem consumes fewer natural resources each year, which translates into a reduced economic burden.

Steam sterilization utilises 32 kWh of electricity and 180,000 litres of water each year; STERRAD™ Systems consume 68–87% less energy and no water at all.[13] The cost savings associated with this can be as much as €8,700 each year per sterilizer.[13]



H_2O_2 avoids the need for lengthy aeration periods that require energy for gentle heat and ventilation of the chamber and operating area, for 8–12 hours, required during EtO sterilization.

Claims requirements of sterilization systems determine the type and number of devices that can be reprocessed in any single cycle. As such, claims requirements may limit the load capacity independent of the size of the chamber. This creates the potential for running partially full cycles, reducing the efficiency of operation, 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, maximises cycle efficiency, potentially further reducing resource expenditure.

High-level disinfection and liquid sterilization do not provide the highest margin of safety, potentially leading to costly HAIs and requiring repeat reprocessing. STERRAD™ Systems avoid pathogen recontamination associated with non-terminal sterilization, and thus the need for repeat reprocessing, ultimately reducing inventory expenditure.

Reducing the Risks Associated with Sterilant Exposure

With no toxic emissions, STERRAD™ Systems avoids the need for measures to protect users, patients and the environment, such as expensive ventilation and abatement systems, and adherence to strict regulatory guidelines, such as for EtO and FO.[25]

Moreover, by utilising gas plasma technology to remove residual H_2O_2, STERRAD™ Systems reduce exposure to potentially harmful residues to safe levels.[26]

STERRAD™ Systems' H_2O_2 emissions, at the user's breathing zone level, are up to 67 times lower than for STERIS V-PRO sterilizers.[26]

Reducing the Economic Burden of HAIs

The high direct costs of HAIs[31] result from increased LOS and utilisation of healthcare resources,[38, 39] and are entirely avoidable.

Compared to treating patients without infection, community post-operative care is more intensive for patients with SSI:

2-fold increase in GP time per patient[39]

5-fold increase in community nurse time per patient[39]

5-fold increase in the likelihood of hospital readmission[40]

The ASP Ecosystem addresses factors contributing to these significant figures and could therefore alleviate the economic burden associated with HAIs.

STERRAD™ Systems deliver the necessary log kill values required to provide the highest margin of safety against HAIs borne from highly contaminated devices.

STERRAD™ Systems maximises safety for all surgical devices, whether used in critical or semi-critical procedures.

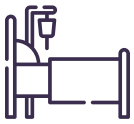
STERRAD VELOCITY™ assures sterility of devices within 30 minutes, allowing CSSD managers to optimise patient safety whilst keeping up with hospital demands.

By inflicting less damage, STERRAD™ Systems may have the potential to reduce the risk of biofilm formation.

A study investigating the burden of SSIs in France found that an annual 8% reduction in HAIs could save:[30]

20,000 bed days

€4.6 million



Summary

There is an unmet need for a sterilization process that can help to avoid harmful and costly HAIs, in a timely and cost-efficient manner, whilst ensuring patient safety.

The ASP™ Ecosystem comprises key features – STERRAD™ Systems with ALLClear™ Technology, ASP ACCESS™ and STERRAD VELOCITY™ – which improve device turnaround time and workflow efficiency, enhancing patient care whilst meeting the demands of the OR.

STERRAD™ Systems maximise device turnover, minimise device repair/replacement, and require less natural resource than alternative reprocessing modalities, ultimately improving cost-efficiency.

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