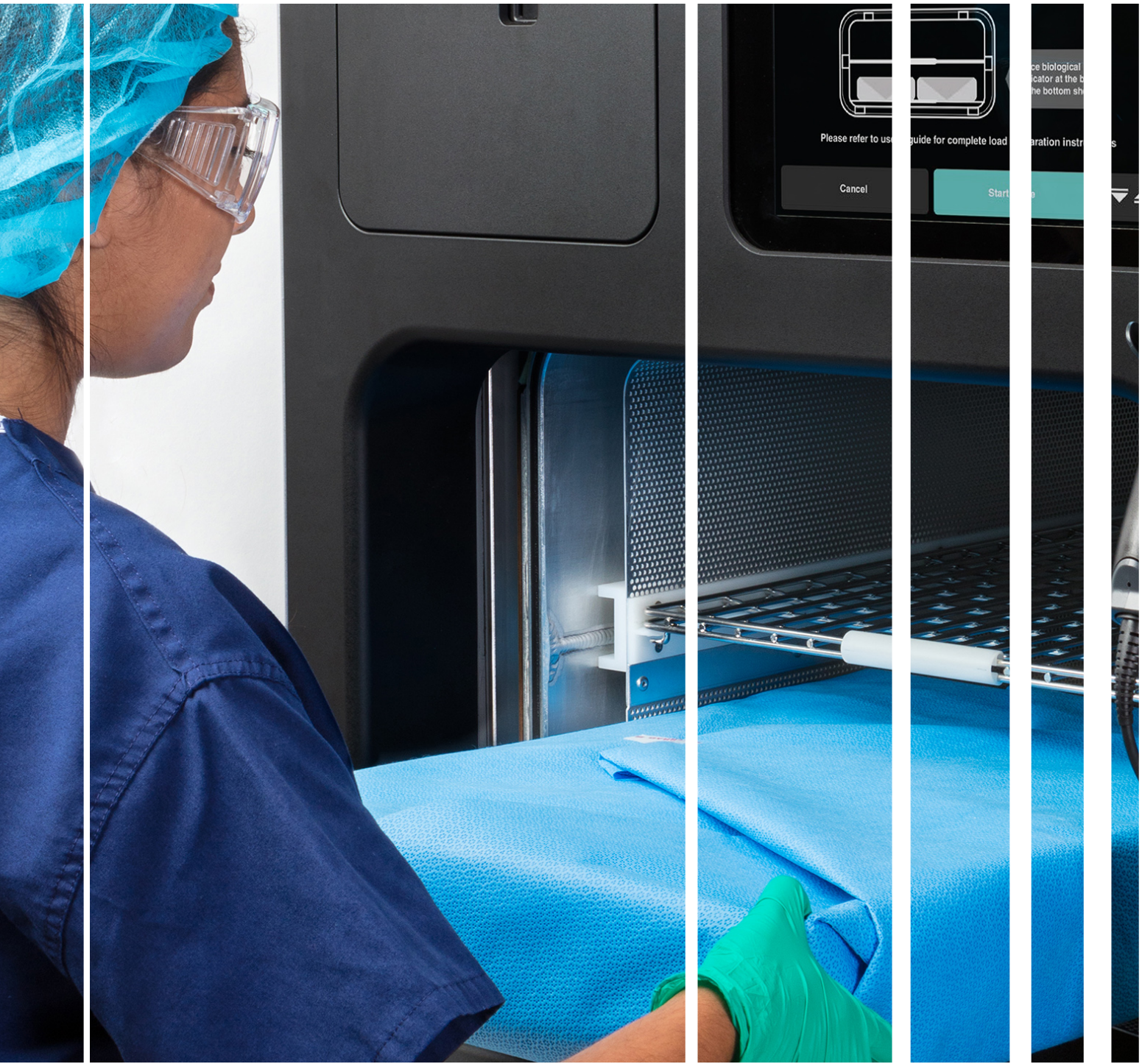
Choosing the Right Reprocessing System for Your CSSD

ASP® Advanced Sterilization Products

The ASP Solution: efficiency, compliance and peace of mind



Choosing the Right Reprocessing System

Addressing the Unmet Need within the Central Sterile Service Department (CSSD)

Healthcare associated infections (HAIs) represent an important patient and financial burden, and a significant proportion of these is related to medical device reprocessing.[1-5]

In Europe, the average prevalence of HAIs is 7.1%, with **4 million** patients affected by HAIs every year.

22% of all surgical site infections are related to equipment reprocessing.

The CSSD therefore plays a critical role in ensuring patient safety by providing sterile devices for use in surgical procedures.

There are many types of reprocessing modalities, including high level disinfection (HLD), high temperature sterilization such as steam, and low-temperature sterilization (LTS), such as ethylene oxide (EtO) and hydrogen peroxide (H_2O_2); each of these are associated with advantages and disadvantages.

Although convenient, HLD does not provide the highest margin of safety, potentially leading to costly HAIs and requiring repeat reprocessing, wasting money and time.

Sterilization offers the greatest margin of safety to device reprocessing, yet conventional methods such as steam are not suitable for all devices, due to the materials used or their complex design. LTS modalities better maintain device integrity, however, each is associated with potential limitations. For example, EtO and its residues are linked with acute and long-term toxicities and are carcinogenic. Sterilization facilities must therefore comply with strict regulations, and implement various precautions, impacting instrument turnover and requiring larger, costly inventories.

Critically, two systems which utilise the same sterilant are not equivalent either, and one may possess distinct advantages over the other. For example, the mechanism of action, capacity and wider features of H_2O_2 sterilizers can vary, leading to differences in safety, speed and efficiency, which all drive the value of the system.

In many CSSDs, there is an unmet need for a reprocessing modality that can help to minimise harmful and costly HAIs and improve CSSD efficiency, safety and compliance. To address this unmet need, as no two reprocessing systems are the same, each CSSD must decide which modality and system best meets its requirements without compromising patient safety.

The ASP Solution

The ASP Ecosystem comprises innovative technologies to optimise device reprocessing. ASP ACCESS™ technology enables automated reconciliation of STERRAD VELOCITY™ biological indicator (BI) results and cycles processed in STERRAD™ Systems with ALLClear™ Technology, and communicates results between connected devices.

STERRAD™ Sterilization Systems

STERRAD™ Systems utilise hydrogen peroxide (H_2O_2) gas plasma in a dry low-temperature (<55°C) environment to sterilize medical devices, producing only safe by-products.

STERRAD 100NX™ is designed to reprocess a large number of instruments quickly, safely and efficiently to meet growing reprocessing demands.

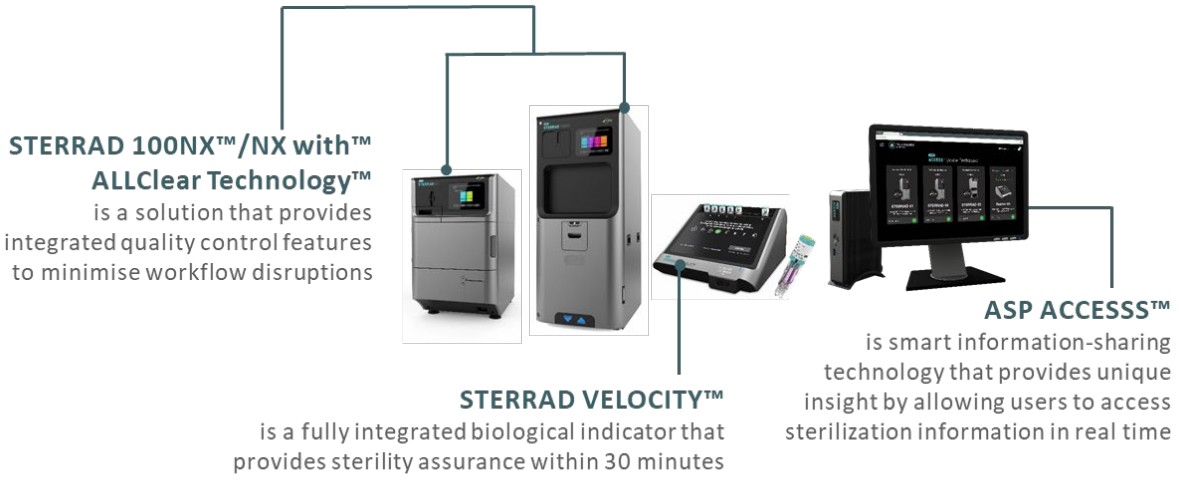
STERRAD NX™ provides speed and flexibility in a space-efficient, compact size, and can easily be cart-mounted and moved for use anywhere in the hospital. Both systems feature:

> ALLClear™ Technology, an innovative software, minimising workflow interruptions and cycle cancellations.

> Connectivity with ASP systems, hospital network and instrument tracking systems, enhancing compliance and optimising productivity.

> An H_2O_2 monitor, facilitating direct measurement of chamber sterilant concentration.

In addition, sterilizer compatibility is guaranteed for each specific device using the STERRAD™ Sterility Guide (SSG), a global, online database of over 23,000 validated devices from over 100 different medical device manufacturers.



ASP ACCESS™

ASP ACCESS™ is a smart, information-sharing technology designed to optimise productivity and enhance compliance by connecting ASP devices to each other, users and hospital systems.

Connectivity: access to cycle records and status of BI from a networked computer in real-time.

Information-sharing: automatic communication of cycle results to networked devices and sharing of sterilization records between sites.

Compliance: automatic reconciliation of sterilization records keeps data audit-ready, and digital reports reduce the risk of human error.

Optimised efficiency: data generated into charts and tables, and expanded access to cycle records allowing identification of the root cause of cancellations.

STERRAD VELOCITY™

STERRAD VELOCITY™ is a fully integrated Process Challenge Device (PCD)/BI that gives CSSD managers and staff the confidence that the reprocessing system complies with infection control guidelines.

Sterility assurance: the only 2-in-1 PCD/BI, designed to create a threshold equivalent to the most challenging location in the most challenging device.

Rapid BI readout: requires ≤30 minutes* to generate results, permitting rapid release of sterile devices.

Compatibility: both sterilizer and indicator technologies, including future enhancements, are seamlessly supported by ASP.

Ease of use: on-board barcode scanner, on-screen display and audible alerts, as well as text and email alerts for critical information.

*A 15-minute version of STERRAD VELOCITY™ BI/PCD readout time will be available soon.

STERRAD™ Systems Versus HLD

Sterilization provides the highest possible margin of reprocessing safety and therefore minimises HAI risk and related health consequences such as increased mortality rates and increased chance of admission to intensive care unit (ICU).

More HAIs have been linked to inadequately cleaned or disinfected endoscopes undergoing HLD than any other medical device.[6] The number of HAIs related to contaminated devices is also increasing, with some recent outbreaks caused by disinfectant-resistant pathogens.[7, 8]

There are a number of reasons why HLD can cause such outbreaks:

- HLD is labour-intensive and steps can be easily neglected;
- HLD does not provide the log kill values required to protect patients;
- Some devices which are used semi-critically and therefore undergo HLD may also be used critically;
- The complex design of certain endoscopes means that they are difficult to disinfect, leading to potential HAI hotspots.

There has recently been a shift in the recommendations of many significant clinical organisations and societies towards the use of sterilization as the standard for endoscope reprocessing.[9, 10] In 2015, the US FDA updated their guidelines to advise that even devices used semi-critically should be sterilized if possible.[9]

Sterilization by STERRAD™ Systems greatly exceeds the reprocessing requirements for highly contaminated semi-critical devices, such as bronchoscopes and gastroscopes, delivering the necessary log kill values required to provide patients with the highest margin of safety against HAIs regardless of the intended subsequent use.[6]

An outbreak of ***P. aeruginosa*** at a teaching hospital in Georgia, USA was traced back to a bronchoscope with internal damage, making the contamination **resistant to HLD** reprocessing.

Sterilization of devices with both non-critical and semi-critical components with STERRAD™ Systems protects patients against HAI outbreaks caused by cross-contamination from non-critical components.[11]

Sterilization by STERRAD™ Systems also reduces the incidence of device-related HAIs in the eventuality that a procedure turns unexpectedly invasive,[9, 12] for example, if a patient suffers a bleed during surgery, and protects patients against HAIs when the subsequent use of a device is unknown.

STERRAD™ Systems Versus Steam

Sterilization of medical devices by dry, low-temperature STERRAD™ Systems reduces the cost impact and HAI risk associated with device damage resulting from moist, high-temperature steam sterilization.

In one US hospital, steam sterilization resulted in

34 battery replacements over a 6-month period at a cost of more than $8,500.[13]

Compared to steam sterilization, STERRAD™ Systems can save on costs associated with device damage:

58% risk reduction of damage;[14]

33% risk reduction in repair costs;[15]

50% reduction in replacement rate.[16]

Instruments damaged by sterilization can also put patients at risk of harm. Steam sterilization damages modern heat- and moisture-labile devices, as well as heat- and moisture-stable devices over time.[17, 18] Damaged components act as hot spots for biofilm formation, and can lead to HAI outbreaks.[19]

> Microsurgical scissors have been demonstrated to exhibit signs of corrosion of the stainless steel cutting surface, suggesting severe oxidation, after 30 cycles of steam sterilization.[18]

By limiting device damage, STERRAD™ Systems can minimise the incidence of HAIs and associated health risks.

Compared to steam sterilization, STERRAD™ Systems can also reduce utilisation of scarce natural resources.[20] Testing of three STERRAD™ sterilizers demonstrated that they all used much less energy compared to a steam sterilizer processing the same reference workload, and no water.[20]

> Unlike steam sterilizers, STERRAD™ Systems do not consume any water to operate and could save 180,000 litres of water per year.[20]

> In comparison to steam sterilization, STERRAD™ Systems consume up to 87% less energy.[20]

> Given the reduced utilisation of natural resources, sterilization of devices with STERRAD™ Systems instead of steam sterilization can bring about savings of as much as €8,700 each year per sterilizer.[20]

By reducing device damage and sparing natural resources, sterilization with STERRAD™ Systems reduces costs compared with steam sterilization.

STERRAD™ Systems Versus Ethylene Oxide (EtO)

EtO is toxic, carcinogenic and associated with ozone depletion;[21] the highest occupational exposure levels are seen during sterilization.[22] Acute exposure can lead to vomiting, and bronchitis.[23] Moreover, long-term, repetitive exposure has been shown to be associated with reproductive disorders, cataracts and neurological disorders.[23] In addition, EtO is considered carcinogenic by the World Health Organisation;[24] increased cancer rates and mortality have been reported from a cohort of more than 18,000 employees exposed to EtO, mainly in sterilization processes.[25]

EtO can also be absorbed by medical devices, leading to complications such as burns and allergic reactions.[22]

Concentrations of unchanged EtO have been measured in sterilized devices.[22]

1–2% EtO

Toxic anterior segment syndrome (TASS) has occurred as a result of EtO-sterilized vitrectomy packs.[26]

19/893 eyes had TASS

Due to the health, safety and environmental concerns associated with EtO, the CSSD must comply with strict regulations.[12, 27-30] While the risks associated with EtO sterilization can be mitigated, putting these measures in place can have the consequence of negatively impacting the CSSD and surgeons.

> EtO sterilization is slow to turnaround instruments due to lengthy cycle times – typically 16–17 hours[31] – driven by the need to aerate the load to help remove toxic residues.[31]

> EtO sterilization requires ventilation and abatement systems, and staff must undergo extensive training, as well as regular health checks, incurring significant costs.[32]

In contrast to EtO, sterilization of medical devices by STERRAD™ Systems eliminates harmful sterilization residues, protecting patients, users and the environment. As a result, STERRAD™ Systems do not require lengthy aeration periods and, in combination with a rapid sterilization cycle (24–60 minutes), can enhance device turnover – up to 21 times that for EtO.[31, 33] By reprocessing devices quickly for safe re-use, STERRAD™ Systems ensure that sterile devices are always available and reduce the demand for large, costly device inventories. As a result, STERRAD™ Systems may help to avoid delays to operating schedules, increasing the throughput of patients.

STERRAD™ Systems help avoid:

- Exposing users and patients to unnecessary severe health risks;
- The need for lengthy aeration periods;
- Large and costly inventories;
- Delays to operating schedules.

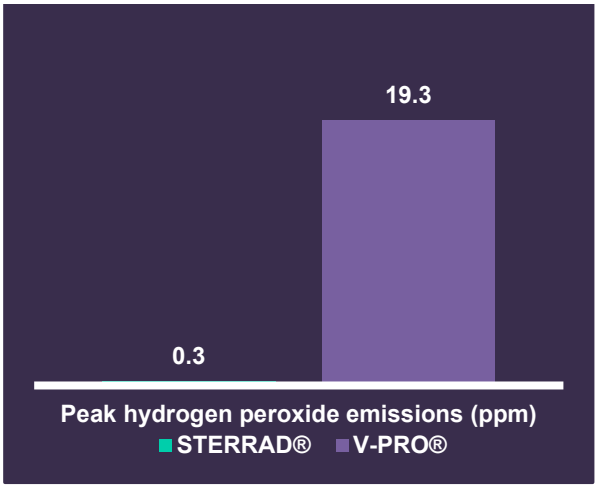
STERRAD™ Systems Versus Other H_2O_2 Sterilizers

Not all H_2O_2 sterilizers are equal; their mechanism of action, capacity and wider features can vary, leading to differences in safety, speed and efficiency, which all drive the value of the system.

Compared to other H_2O_2 sterilizers, STERRAD™ Systems are more effective in limiting H_2O_2 emissions, contributing to a safer working environment.

STERRAD™ Systems are **67x** more effective in limiting H_2O_2 emissions compared to alternative H_2O_2 sterilizers.[34]

STERIS V-PRO® sterilizers have been shown to produce instantaneous peak measurements of H_2O_2 up to 20 ppm at the user's breathing zone level, above that deemed safe by the ACGIH.[34] In contrast, by utilising gas plasma technology to remove residual H_2O_2, STERRAD™ Sterilization Systems reduce exposure to harmful residues, to safe levels.[34]



Compared to other H_2O_2 sterilizers, STERRAD™ Systems improve device turnover, contributing to a more efficient working environment.

> Conventional 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, putting patients at risk of harm or delaying scheduled procedures.

> With a BI readout of 30 minutes or less*, STERRAD™ Systems provide fast instrument turnaround, allowing CSSD managers to optimise patient safety whilst keeping up with hospital demands.

> Claims requirements of other H_2O_2 sterilizers 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 turnaround time.

The STERRAD 100NX™ system is permitted to hold **40** lumens per load,[35] while the STERIS V-PRO® maX system can only hold **20**.[36]

*A 15-minute version of STERRAD VELOCITY™ BI/PCD readout time will be available soon.

Unlike many other LTS companies that rely on assumed compatibility, ASP collaborates with medical device manufacturers to validate devices for sterilization with each STERRAD™ sterilizer and cycle. The SSG only lists devices that have been suitably tested, including complex devices that pose challenges for conventional reprocessing modalities and the highest demand devices crucial to delivery of care which require rapid turnaround.

The SSG is a global, online database of devices that meet STERRAD™ System claims, and lists over **23,000** validated devices from over **100** different medical device manufacturers.

The SSG and the 2-in-1 PCD/BI, which stimulates a greater challenge than or equal to your most challenging instrument to sterilize, provides CSSDs the confidence that risk of patient harm is minimised.

The Value of the ASP Solution

The ASP Ecosystem provides sterility assurance with the challenge of a PCD combined with a BI within 30 minutes or less. It is the only sterilization system that automatically reconciles sterilization cycle and BI records and subsequently communicates the information between sterilizers, the BI readout system and instrument tracking networks.

Compared to other reprocessing systems, the ASP Ecosystem is in a unique position to help CSSDs improve patient, user and environmental safety whilst also maximising workflow efficiency and compliance.

Sterilization by STERRAD™ Systems:

- Contributes to optimising patient safety and addresses risk factors, including unexpected use in critical procedures and contamination hotspots, for HAIs.
- Contributes towards cost savings through low natural resource utilisation and through gentle sterilisation that protects devices and avoids repair and replacement costs.
- Turns instruments around quickly and has appropriate capacity claims, helping to drive reprocessing throughput.
- Protects staff against H_2O_2 emissions, and produces safe, biodegradable by-products, contributing to a safe work environment.

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