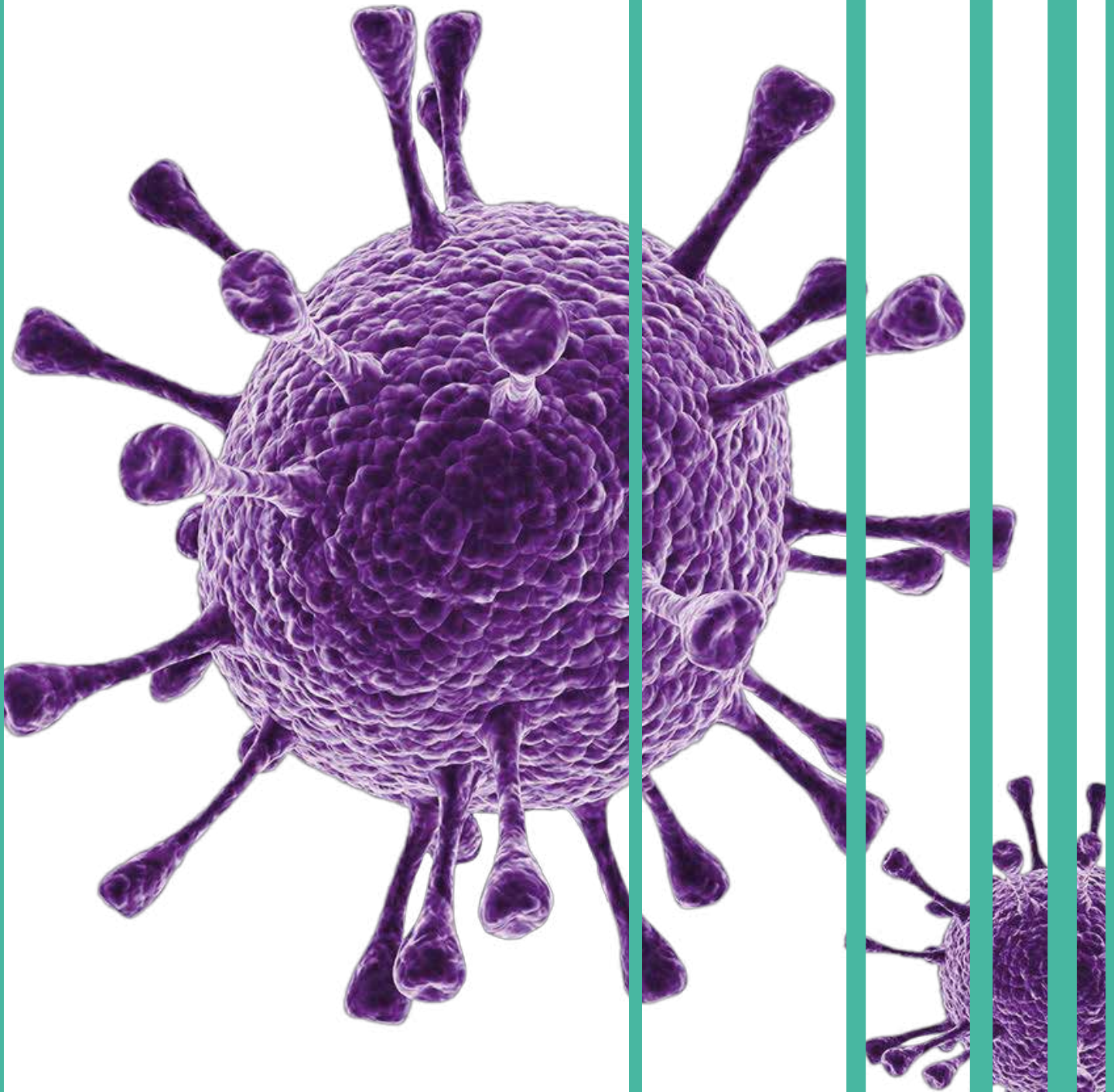


# Challenges of Medical Device Reprocessing

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An overview of the evidence and leading technologies to minimise the impact



# Understanding the Challenges of Medical Device Reprocessing

## Healthcare-Associated Infections are a Major Global Safety Concern

Healthcare-associated infections (HAIs) can occur in patients receiving medical care and are associated with significant morbidity, mortality and healthcare costs.<sup>1</sup> They are an alarming safety concern, representing the most frequent adverse event in healthcare delivery worldwide.<sup>1</sup> In Europe, the average prevalence of HAIs is 7.1%, with more than 4 million patients affected by HAIs every year.<sup>1</sup> However, given the acknowledged reporting gaps in existing surveillance systems, the scale of the problem is considered to be greatly underestimated.<sup>2</sup>

HAIs prolong hospital stays, cause long-term disability, increase antimicrobial resistance, cause unnecessary deaths and represent a significant financial burden for health systems.<sup>3</sup>

### Annually, across Europe, HAIs cause:



**16 million** extra days of hospital stay<sup>1</sup>



**€7 billion** in healthcare cost alone<sup>2</sup>



**37,000** deaths, whilst contributing to a further **110,000** deaths<sup>1</sup>

In order to understand how to prevent HAIs from occurring in the first place, we need to know what causes them. The occurrence of HAIs is indeed complex; factors can be categorised into environmental, patient and healthcare-related and clearly, a multimodal approach is required to tackle them.<sup>4</sup>

## Inadequate Medical Device Reprocessing is a Preventable Source of Healthcare-Associated Infections

Despite the existence of reprocessing guidelines and advances in device reprocessing methods, inadequate reprocessing of medical devices contributes to a significant proportion of HAIs. In fact, 22% of all surgical site infections (SSIs), one of the most common types of HAI,<sup>5</sup> are related to equipment reprocessing.<sup>6-10</sup> A significant proportion of these HAIs is considered preventable.<sup>11</sup>

Even with clear advances in preventative procedures, HAIs arising from medical devices continue to be a problem for hospitals and health care facilities around the world. In this article, we will highlight the key challenges surrounding medical device reprocessing that lead to HAIs, describe the evidence around these challenges, and discuss how leading technologies can minimise the incidence and burden of such infections.

## High-Temperature Sterilization Methods can Damage Devices Deemed Heat- or Moisture-compatible


Whilst many modern devices are deemed unsuitable for high-temperature reprocessing methods such as steam sterilization, some can be deemed compatible despite being sensitive to the harmful physical effects of temperature and humidity. There are reports of such sensitive devices becoming damaged over time,<sup>12, 13</sup> which not only reduces the efficacy of such devices, and therefore the likelihood of a successful procedure, but also exacerbates known risks factors for inadequate sterilization, namely the development of damaged sites that act as hot spots for biofilm formation and potential HAI outbreaks.<sup>14</sup>

However, the impact on patient safety is not the only important consideration. High-temperature sterilization methods such as steam is also energy- and water-intensive.<sup>15-</sup>


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In addition to these wasted costs and resources, the damage to devices caused by steam sterilization can lead to high costs associated with early replacement. One study estimated that a single large-scale healthcare facility could look to spend more than \$1 million over 10 years on repairs of heat-compatible devices that could have been avoided if using a more appropriate reprocessing method.<sup>17</sup>

Steam sterilizers might require **up to 20L** of water per minute of operation.<sup>15</sup>



In one hospital, **34** steam-sterilized batteries had to be replaced over **6 months**,



costing the hospital more than **\$8,500**.<sup>18</sup>

## In Avoiding High Temperatures, Some Low-Temperature Sterilization Methods use Sterilants that may Harm Users and Patients

For the many modern-day devices that cannot tolerate high temperature steam sterilizers, low-temperature sterilization (LTS) methods are available that reprocess devices without exposing them to such high temperatures and humidity, and therefore reduce the risk of device damage. Ethylene oxide (EtO) and formaldehyde gas (FO) are amongst the traditional LTS methods,<sup>19</sup> but present unique challenges of their own. Both use sterilant gases that are considered toxic and carcinogenic by the World Health Organization (WHO),<sup>20</sup> thus putting patients at an avoidable risk of harm if devices are not properly aerated. For example, exposure to EtO or its toxic by-products through contact with reprocessed medical devices has been shown to lead to serious health complications such as allergic reactions, burns<sup>21</sup> and health conditions such as toxic anterior segment syndrome (TASS).<sup>22</sup>

**TASS has occurred as a result of EtO-sterilized vitrectomy packs, leading to the syndrome in 19/893 (2%) eyes studied.**

**In comparison, no TASS cases were observed with non-EtO sterilized packs.<sup>22</sup>**

In addition to the risk these technologies put on patients, the challenges placed on protecting users and the environment and minimising resource use should also be considered.

EtO is associated with high water use, and the lengthy aeration time leads to high electricity use.<sup>23</sup>



Extended aeration leads to very long cycle times; approximately 16 hours. This leads to a low rate of instrument turnover, increasing the demand for large and costly device inventories.



Through high resource use and emission of toxic gases, EtO poses a significant risk to the environment; the US Environmental Protection Agency released regulations in 2007 that aims to reduce air pollution for EtO sterilizers.<sup>21</sup>



## Reprocessing Classifications may be Insufficient to Meet the Needs of Modern-Day Practice

The pragmatic approach to disinfection by Earle H Spaulding historically determines the level of reprocessing required based on the degree of risk involved in their use (Table).<sup>25</sup>

However, with the Spaulding Classification first proposed more than 50 years ago, and the rapid advancements in medical devices, materials science and procedures, this classification may be insufficient to meet the needs of modern-day practice.<sup>25, 26</sup>

It is not uncommon for semi-critical devices to be used critically in surgical procedures; Central Sterile Services Department (CSSD) managers may not always be aware of a device's next use and whether a different reprocessing method would be required. As such these devices that require sterilization may only undergo high-level disinfection (HLD), potentially not eliminating pathogens leading to infections.<sup>26</sup>

Different parts of the same device can have different reprocessing needs. A semi-critical device could also be used in conjunction with a critical device contacting sterile tissue during a procedure.<sup>23</sup>

Semi-critical devices may unexpectedly encounter sterile tissue, for example if bleeding is present. These situations can lead to devices that have only been disinfected being used in a critical environment, putting patients at a preventable risk of infection.

**Inadequate reprocessing of an urological endoscope was identified as the cause a multidrug-resistant NDM-1 Klebsiella outbreak in 12 patients, due to cross-contamination from the 'non-critical' camera head. Sterilization of the entire device was recommended.<sup>27</sup>**

Accordingly, the US FDA now recommends sterilization as the appropriate reprocessing method for semi-critical devices, given it offers the highest margin of safety.<sup>28</sup>

### Overview of Spaulding Classification

Spaulding Classification	Minimum Level of Reprocessing	Rationale	Device Example
<b>Non-critical</b>	Low-level Disinfection	Items only contact intact skin and are used in circumstances where there is virtually no risk of infection transmission	Blood pressure cuffs
<b>Semi-critical</b>	High-level Disinfection	Items contact mucous membranes or non-intact skin and should be free of microorganisms, small numbers of spores may be present	Endoscopes
<b>Critical</b>	Sterilization	Items enter sterile tissues or vasculature and must be free of all microorganisms, including bacterial spores	Surgical forceps

## Limitations in Reprocessing Guidelines that do not Consider all Eventualities

Despite improvements in device reprocessing guidelines, HAIs continue to be a substantial concern. Various factors are not always fully considered in guidelines and impact the success of sterilization:

The complex structures of modern devices make reprocessing more challenging and increase the risk of transmission of HAIs. The FDA have identified design features that are prone to retaining biological debris, including hinges, sleeves, blades, inserts and features that cannot be disassembled.<sup>28</sup>

**Over an 8-month period at two US hospitals, inadequate reprocessing of duodenoscopes led to HAIs in 13 patients. These HAIs were linked back to contamination of the elevator channel. Such small, heat-labile parts are difficult to reprocess and thus contribute to a higher risk of HAIs.<sup>30</sup>**

Manufacturers may not consider how post-market modifications impact the reprocessing method. Poor communication between manufacturers and users when reprocessing instructions for devices are revised may lead to processes being outdated or inadequate.<sup>28</sup>

Complex devices are prone to damage; damaged surfaces serve as HAI hotspots for biofilm formation.<sup>14</sup>

**12 patients contracted *P. aeruginosa* that was traced back to a damaged bronchoscope, despite undergoing suitable HLD.<sup>31</sup>**

The FDA found that many manufacturers designed inadequate test conditions to validate their reprocessing systems. Cleaning of internal components was not always considered as part of design validation.<sup>28</sup>

Some semi-critical devices are simply exposed to such high levels of contamination that HLD is not always capable of effectively reducing the bioburden to safe levels.<sup>32</sup>

**Despite normal HLD, positive bacterial cultures were obtained from biopsy channels of 10.7% (32/300) of gastroscopes and 20.8% (25/120) colonoscopes.<sup>32</sup>**

## A Solution that Addresses the Unmet Needs of Medical Device Reprocessing

Given the challenges described above, there is a clear need for a sterilization process that can help avoid harmful and costly HAIs, protect patients and users, and improve compliance.

ASP offers a unique ecosystem of innovative technologies that address the burden of compliance, efficiency and safety for instrument reprocessing teams, and above all, contributes to a process that aims for the complete prevention of HAIs.

STERRAD™ 100NX and STERRAD NX™ with ALLClear™ Technology are sterilization platforms that provide integrated quality control features to ensure sterility whilst minimising workflow disruptions.

STERRAD VELOCITY™ is a fully integrated Biological Indicator (BI)/Process Challenge Device (PCD) that provides sterility assurance within 15 minutes.



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



Key benefits of the Ecosystem in helping to prevent HAIs include:

STERRAD™ Sterilization Systems involve the combined use of hydrogen peroxide and low-temperature gas plasma to rapidly and safely sterilize medical devices and materials without leaving toxic residues.

The gentler action of STERRAD™ Systems means it is more appropriate for devices that are heat-sensitive, helping to reduce repair costs and prevent device damage hot-spots from forming and potentially harming patients.

**A side-by-side comparison of delicate microsurgical scissors sterilized by steam and STERRAD™ Sterilizer showed that, after 30 reprocessing cycles, the autoclaved scissors demonstrated a noticeable drag in cutting whereas there was no loss of functionality caused by STERRAD™ System reprocessing.<sup>12</sup>**

**When considering purchase price, utilities, maintenance contracts and instrument repairs, sterilizing heat-compatible devices with STERRAD™ Systems instead of steam is estimated to save a hospital \$738,833 over 10 years, driven primarily from reductions in device repair.<sup>17</sup>**

Sterilization with STERRAD™ Systems offers a higher margin of safety compared to non-sterile processes like HLD, which is especially important for devices with

mixed uses or those that are highly contaminated.

The fast read-out of STERRAD VELOCITY™ BI/PCD allows a biological indicator to be processed with every load, providing the confidence that HAI risk is minimised. Automated record keeping allows CSSDs to demonstrate sterility and reduce the risk of liability.

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

The STERRAD™ Sterility Guide is a global, online database of devices that meet STERRAD™ System claims, and includes over 20,000 listings of validated devices from over 100 different medical device manufacturers. Users can be assured that compatibility is guaranteed for each specific device and thus, regardless of complexity or post-market modifications, the risk of patient harm is minimised.

To learn more about the ASP Ecosystem and how it can prevent HAIs, please contact your local ASP sales representative.

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