

SURGICAL INSTRUMENT STERILIZATION: A COMPARATIVE REVIEW OF CONVENTIONAL METHODS AND EMERGING TECHNOLOGIES

Mr. Anayat Ali Dar¹, Mr. Mohd Shafi Sheikh², Ms. Sharmila Palanisamy³, Ms. Deepika B⁴,
Ms. Hephzibah Solomon P⁵

¹Assistant Professor, ²Assistant Professor, ³Research Scholar, ⁴Assistant Professor, ⁵Assistant Professor

¹ATOT, ²School of Life and Health Sciences, ³SRM Medical College Hospital and Research Centre, ⁴School of Allied Health Sciences, ⁵School of Allied Health Sciences

¹Era University, Lucknow, Uttar Pradesh, India, ²Joy University, India, ³SRM Medical College Hospital and Research Centre, India, ⁴VMRF–DU, Chennai Campus, India, ⁵VMRF–DU, Chennai Campus, India

Abstract—Surgical site infections (SSIs) remain among the most significant preventable causes of postoperative morbidity, and the adequacy of surgical-instrument reprocessing is central to their prevention. Sterilization eliminates all forms of microbial life, including bacterial endospores, from reusable critical medical devices prior to reuse. For over a century, saturated steam under pressure (autoclaving) has remained the reference-standard method because of its reliability, low cost and absence of toxic residues; however, an increasing proportion of surgical instrumentation - flexible endoscopes, powered devices, fibre-optic components and heat-labile polymers - cannot withstand steam's temperature and moisture without damage. This has driven continued refinement of conventional low-temperature methods, principally ethylene oxide (EtO) gas and liquid chemical sterilants, alongside the emergence of newer low-temperature technologies including hydrogen peroxide gas plasma, vaporized hydrogen peroxide (VHP), ozone, supercritical carbon dioxide and ionizing radiation. This review synthesises the mechanisms, operating parameters, material compatibility, cycle times, cost and environmental considerations of both conventional and emerging sterilization modalities, drawing on peer-reviewed literature, international standards (ISO, AAMI) and public-health guidance (CDC, WHO). A structured comparative analysis is presented, supported by a process-flow diagram of instrument reprocessing, a representative steam-cycle temperature-pressure profile, a cycle-time comparison chart and an illustrative distribution of modality use in hospital central sterile supply departments (CSSDs). The review finds that no single technology is universally optimal; method selection must balance microbicidal efficacy, material compatibility, turnaround time, capital and operating cost, and operator/environmental safety. Hybrid reprocessing strategies, tighter international standardisation and continued development of low-toxicity, rapid-cycle, low-temperature sterilants represent the most promising directions for improving the safety, throughput and sustainability of surgical instrument sterilization.

Key words—sterilization, surgical instruments, steam autoclaving, ethylene oxide, hydrogen peroxide plasma, infection control, central sterile supply department

INTRODUCTION

Every invasive surgical procedure exposes a patient to the risk of pathogenic microorganisms being introduced through contact between a medical device and normally sterile tissue. Reusable surgical instruments are classified, under the widely adopted Spaulding scheme, as “critical” items because they penetrate skin or contact sterile tissue, and must therefore be rendered completely free of all viable microorganisms, including bacterial spores, before reuse. Sterilization is distinguished from disinfection by this absolute microbicidal endpoint: high-level disinfection reduces microbial burden and may tolerate a small population of resistant spores, whereas sterilization is

defined by an internationally standardised probability of a non-sterile unit no greater than one in one million (a Sterility Assurance Level, SAL, of 10^{-6}).

Surgical site infections and other device-associated infections remain a leading cause of preventable postoperative morbidity, prolonged hospitalisation and increased healthcare cost, and inadequately reprocessed instruments have repeatedly been implicated in outbreak investigations, particularly involving complex, lumened or heat-sensitive devices such as flexible endoscopes and powered surgical tools. As surgical technology has diversified - incorporating fibre-optics, electronic components, adhesives and heat-labile polymers that cannot tolerate the high temperature and moisture of conventional steam sterilization - the range of sterilization technologies available to Central Sterile Supply Departments (CSSDs) has expanded correspondingly.

This review has three objectives: first, to summarise the operating principles, parameters and evidence base of conventional sterilization methods - saturated steam, dry heat, ethylene oxide gas and liquid chemical sterilants; second, to review emerging low-temperature and physical sterilization technologies, including hydrogen peroxide gas plasma, vaporized hydrogen peroxide, ozone, ionizing radiation and supercritical carbon dioxide; and third, to present a structured comparative analysis - spanning cycle time, material compatibility, residual toxicity, cost and environmental impact - to support evidence-based method selection in clinical and industrial sterile-processing settings. Figure 1 outlines the generalised instrument-reprocessing workflow within which every sterilization technology discussed in this review is embedded.

CONVENTIONAL STERILIZATION METHODS

A. Steam Sterilization (Autoclaving)

Saturated steam under pressure remains the most widely used, most extensively validated and generally least expensive method for sterilizing heat- and moisture-stable surgical instruments. Microbial inactivation occurs primarily through hydrolysis and coagulation of proteins and nucleic acids, a process greatly accelerated by the latent heat released as steam condenses on cooler instrument surfaces. Two principal cycle types are in clinical use: gravity-displacement cycles, in which steam displaces air downward through a drain, and dynamic-air-removal (pre-vacuum) cycles, in which a series of vacuum pulses actively evacuates air before steam admission, giving more reliable penetration of porous loads and lumened devices. Typical validated cycle parameters are 121°C for 15-30 minutes (gravity) or 132-134°C for 3-10 minutes (pre-vacuum), as governed by ISO 17665 and AAMI ST79. Advantages include rapid cycles, non-toxic byproducts, low per-cycle cost and a mature ecosystem of biological indicators (typically *Geobacillus stearothermophilus* spores) and chemical indicators for routine quality assurance. Limitations include unsuitability for heat- or moisture-labile items, the risk of “wet packs” compromising sterile packaging, and progressive corrosion of certain instrument alloys with repeated cycling.

Figure 1: Generalized Workflow for Reprocessing of Reusable Surgical Instruments

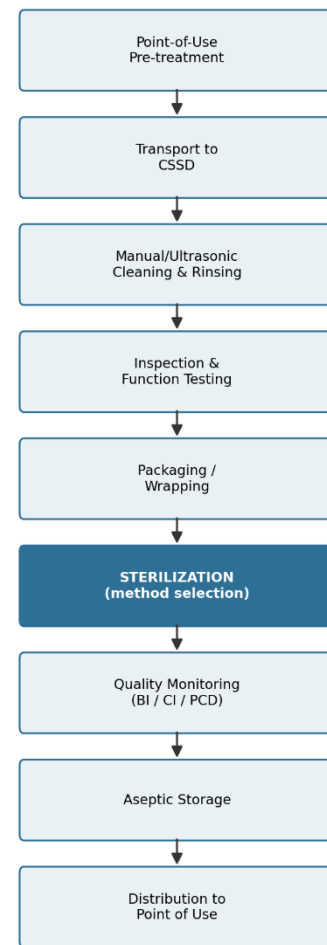


Figure 2: Representative Time-Temperature-Pressure Profile of a Gravity-Displacement Steam Sterilization Cycle (134°C, 3-min hold)

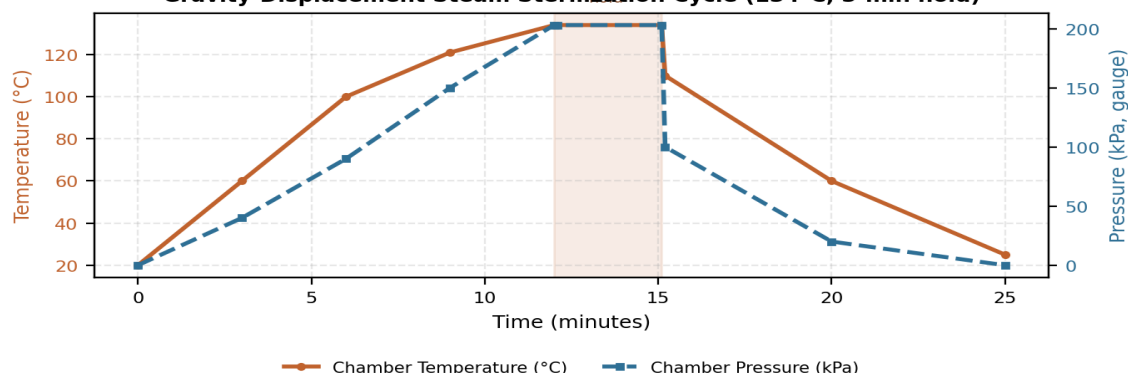


Figure 2: Representative time-temperature-pressure profile of a gravity-displacement steam sterilization cycle (134°C, 3-min hold).

B. Dry Heat Sterilization

Dry heat sterilizes by prolonged oxidative destruction of cellular constituents in a convection or forced-air oven, typically at 160-190°C for 60-150 minutes depending on temperature and load. Because no moisture is involved, it is well suited to anhydrous materials such as oils, powders, and to sharp metal instruments that would corrode or dull under repeated steam exposure. Its principal drawbacks are long cycle times, high energy consumption, and incompatibility with most plastics, rubbers and heat-sensitive polymers, which restricts its contemporary role to a narrow range of specialised applications.

C. Ethylene Oxide (EtO) Gas Sterilization

EtO sterilizes through alkylation of nucleic acids and proteins, a reaction that proceeds efficiently at low temperature (37-63°C) and therefore suits heat- and moisture-sensitive devices, complex lumens and electronic components that steam would damage. Cycles combine controlled humidity, gas concentration and exposure time (commonly 1-6 hours) but must be followed by an extended aeration period - typically 8-12 hours - to desorb residual EtO and its reaction products (ethylene chlorohydrin, ethylene glycol), both of which are toxic and, in the case of EtO itself, classified as a human carcinogen. This residue-and-aeration burden, together with the flammability of pure EtO (commonly mitigated with inert carrier gases) and tightening regulatory limits on facility emissions, has been a major driver of interest in the low-temperature emerging technologies discussed below. EtO sterilization is standardised internationally under ISO 11135.

D. Chemical / Liquid Sterilants

Liquid chemical sterilants - principally glutaraldehyde and peracetic acid, with ortho-phthalaldehyde used chiefly as a high-level disinfectant - act through oxidative cross-linking or alkylation of microbial macromolecules and are used mainly for immersion reprocessing of heat-sensitive flexible endoscopes, either manually or in automated endoscope reprocessors. Peracetic acid-based automated systems (e.g., single-use, buffered peracetic acid immersion systems) can achieve a true sterilization endpoint at near-ambient temperature within roughly 25-50 minutes. Limitations include the need for thorough post-exposure rinsing to remove toxic residues, respiratory and mucosal irritation risks for reprocessing staff, absence of packaging for storage (necessitating near-immediate use for manually processed items), and material compatibility limits with certain adhesives and lens cements.

EMERGING STERILIZATION TECHNOLOGIES

A. Low-Temperature Hydrogen Peroxide Gas Plasma

In this technology, vaporized hydrogen peroxide is introduced into an evacuated chamber and, in a second phase, excited into a low-temperature plasma state by radiofrequency or microwave energy. The plasma generates reactive species - hydroxyl and hydroperoxyl radicals in particular - that enhance microbicidal action while simultaneously breaking down residual hydrogen peroxide into water and oxygen, leaving no toxic residue and eliminating the need for aeration. Typical cycles run 45-75 minutes at 45-50°C, making the method attractive for heat- and moisture-sensitive rigid endoscopes, powered instruments and electronic devices. Key limitations are incompatibility with cellulose-based materials (paper, linen, which absorb the peroxide) and reduced penetration into long, narrow lumens without diffusion-enhancing accessories.

B. Vaporized Hydrogen Peroxide (VHP)

VHP shares the oxidative chemistry of gas-plasma systems without a discrete plasma-generation step, and is used both for point-of-use sterilization of packaged instruments (cycles of roughly 28-55 minutes) and, at larger scale, for whole-room or enclosure bio-decontamination. Byproducts are again water and oxygen. VHP systems attracted considerable attention as a large-scale decontamination option for filtering-facepiece respirators during periods of critical supply shortage, illustrating the flexibility of the underlying chemistry beyond conventional instrument reprocessing.

C. Ozone Sterilization

Ozone is a powerful oxidant that can be generated on demand from oxygen and ambient humidity within the steriliser itself, avoiding the need to store a sterilant precursor. It inactivates microorganisms by oxidising membrane lipids, proteins and nucleic acids at a comparatively mild 30-36°C, and decomposes spontaneously back to oxygen, leaving no chemical residue. Its principal disadvantage relative to other low-temperature methods is a considerably longer cycle - typically around 4 to 4.5 hours including humidification, exposure and aeration/venting phases - which limits throughput in high-volume CSSDs despite its favourable environmental and safety profile.

D. Ionizing Radiation Sterilization (Gamma and Electron-Beam)

Gamma irradiation (from a cobalt-60 source) and electron-beam (e-beam) irradiation inactivate microorganisms by directly and indirectly damaging DNA through ionization. Both are used predominantly for industrial, manufacturer-level sterilization of single-use devices and bulk-packaged goods rather than for point-of-care hospital reprocessing of reusable instruments. Gamma radiation offers high penetration and is delivered continuously over minutes to an hour depending on dose rate, requiring no aeration; e-beam delivers an equivalent dose within seconds to a few minutes but has lower penetration depth, restricting it to thinner or lower-density loads. Repeated radiation exposure

can embrittle certain polymers, which, together with the substantial capital cost of irradiation facilities, limits routine radiation sterilization to manufacturing rather than hospital reprocessing contexts. The method is standardised under ISO 11137, and X-ray sterilization is emerging as a source-free alternative offering deeper penetration than e-beam.

E. Supercritical Carbon Dioxide (scCO₂) Sterilization

Above its critical point (31.1°C, 7.39 MPa), carbon dioxide exhibits liquid-like solvating power and gas-like diffusivity, allowing it to penetrate microbial cells and, particularly when combined with a small quantity of an oxidising additive such as peracetic acid, disrupt membranes and denature proteins at near-ambient temperature. Because it operates at low temperature, is non-flammable, non-toxic and leaves no residue on venting, scCO₂ is being actively investigated for heat-sensitive polymers, biologics and combination drug-device products for which existing low-temperature methods are unsuitable or slow. It remains, however, at a comparatively early stage of clinical and regulatory maturity relative to steam, EtO or hydrogen-peroxide-based technologies, with capital equipment cost and standardisation still developing.

F. Cold Atmospheric Plasma and Nanotechnology-Enabled Approaches

Cold atmospheric-pressure plasma, generated in ambient air or noble/reactive gas mixtures without the need for a vacuum chamber, produces reactive oxygen and nitrogen species capable of rapid, low-temperature microbial inactivation, and is being explored as a portable, point-of-use option for complex-geometry or robotic-assisted surgical instruments, though it remains largely at the research and pre-commercial stage. In parallel, nanotechnology-enabled surface treatments - including photocatalytic titanium-dioxide coatings activated by ultraviolet light and silver- or copper-based nanoparticle coatings - are being investigated to confer continuous antimicrobial or self-sterilizing properties to instrument housings and high-touch surfaces. These approaches are intended to complement, rather than replace, terminal sterilization of patient-contact working surfaces, and long-term biocompatibility and regulatory pathways for nanomaterial-coated reusable instruments remain areas of active investigation.

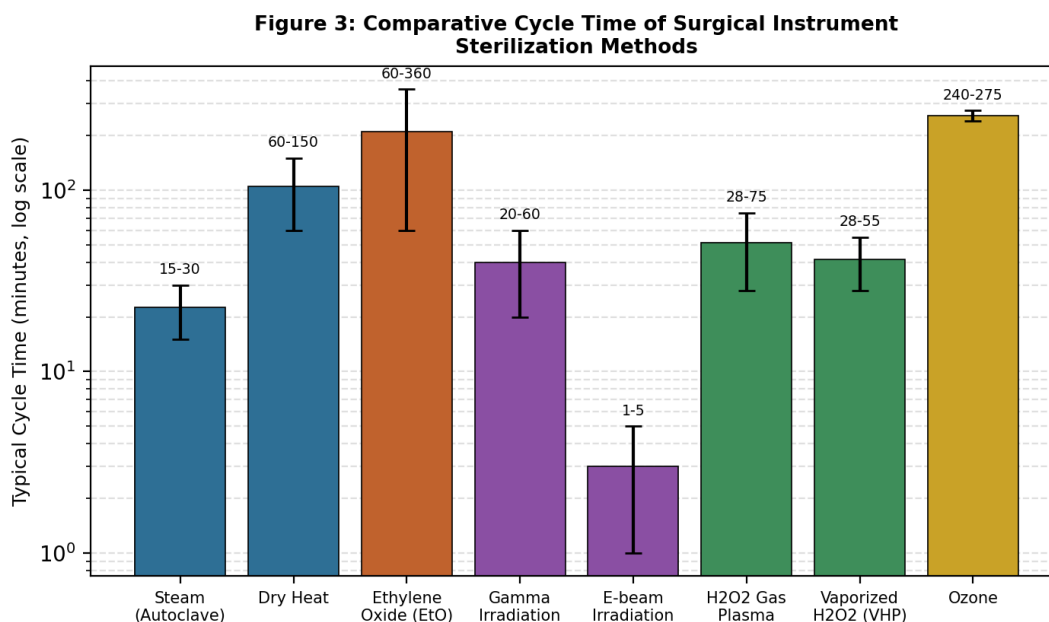


Figure 3: Comparative cycle time of surgical instrument sterilization methods (log scale; EtO/ozone exposure time excludes EtO aeration).

COMPARATIVE ANALYSIS

Table 1: Comparative Summary of Conventional and Emerging Surgical Instrument Sterilization Methods

Method	Mechanism of Action	Operating Temp.	Typical Cycle Time	Material Compatibility	Toxic Residue	Relative Cost	Environmental Footprint
Steam (Autoclave)	Protein coagulation & hydrolysis by moist heat	121-134°C	15-30 min	Metals, glass, textiles; not heat/moisture-labile items	None	Low	Low (water/energy only)
Dry Heat	Oxidation of cellular constituents	160-190°C	60-150 min	Anhydrous items, oils, powders, sharp metals	None	Low-Moderate	Low; high energy use
Ethylene Oxide (EtO)	Alkylation of DNA/proteins	37-63°C	1-6 h + 8-12 h aeration	Wide range incl. plastics, electronics, lumened devices	Carcinogenic EtO/ECH residues	Moderate	High (VOC/GHG; regulated emissions)

Method	Mechanism of Action	Operating Temp.	Typical Cycle Time	Material Compatibility	Toxic Residue	Relative Cost	Environmental Footprint
Gamma / E-beam Irradiation	Ionizing radiation causes DNA strand breaks	Ambient	Min-1 h (industrial)	Single-use polymers, packaged bulk goods	None (may embrittle polymers)	High (capital)	Moderate (source/energy mgmt.)
H2O2 Gas Plasma	Free-radical oxidation of cell components	45-50°C	45-75 min	Heat/moisture-sensitive devices; not cellulose/long narrow lumens	None (H2O + O2 byproducts)	High	Low
Vaporized H2O2 (VHP)	Oxidative disruption by H2O2 vapour	30-50°C	28-55 min	Heat-sensitive devices; surfaces/rooms	None (H2O + O2 byproducts)	Moderate-High	Low
Ozone	Strong oxidation of membranes/enzymes	30-36°C	240-275 min	Wide range of heat-sensitive metals/plastics	None (decomposes to O2)	Moderate	Very Low (on-site generation)
Supercritical CO2	Membrane disruption under supercritical CO2 ± additive	~35-40°C	30-90 min (emerging)	Heat-sensitive polymers, biologics, combination products	None reported	High (capital; emerging)	Very Low

Figure 4: Approximate Share of Sterilization Modalities in Hospital Central Sterile Supply Departments (CSSD)

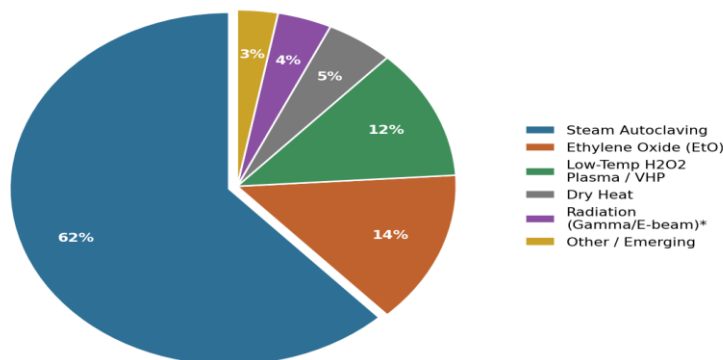


Figure 4: Approximate share of sterilization modalities in hospital Central Sterile Supply Departments (CSSD); illustrative distribution synthesised from the reviewed literature.

Table 1 and Figures 3-4 summarise the comparative profile of the eight modalities reviewed above. Two broad patterns emerge. First, there is a persistent trade-off between cycle time and material compatibility: the fastest, cheapest and best-characterised method (steam) remains unsuitable for an expanding share of modern instrumentation, while the low-temperature alternatives that accommodate heat-sensitive devices generally impose longer cycles, higher capital cost, or - in the case of EtO - a substantial toxic-residue and aeration burden. Second, the newer hydrogen-peroxide-based technologies (gas plasma and VHP) currently offer the most favourable overall balance for heat-sensitive rigid instrumentation, combining moderate cycle times with non-toxic byproducts, which explains their growing share of CSSD workload illustrated in Figure 4. Ozone, radiation and supercritical CO₂ occupy more specialised niches, valuable where their particular strengths (residue-free chemistry, industrial-scale throughput, or ambient-temperature processing of biologics, respectively) outweigh their limitations in cycle time, penetration or maturity.

ILLUSTRATIVE CASE APPLICATION

Consider a tertiary-care CSSD that historically relied on EtO for its growing volume of heat-sensitive laparoscopic and robotic-assisted instrumentation. Extended EtO aeration times were increasingly identified as a throughput bottleneck for high-turnover operating theatres, while tightening facility emission limits raised recurring compliance costs. Transitioning a defined subset of compatible, non-lumened or wide-lumen instrumentation to a low-temperature hydrogen-peroxide gas-plasma system reduced total turnaround time for that instrument subset from a multi-hour EtO-plus-aeration cycle to under 90 minutes, while eliminating aeration-related toxic-residue monitoring for those loads. EtO was retained for long, narrow-lumen and cellulose-containing loads incompatible with plasma chemistry, illustrating the more general principle that most CSSDs of any scale benefit from maintaining two or more complementary sterilization modalities rather than relying on a single technology across all instrument types.

CHALLENGES AND FUTURE DIRECTIONS

Several challenges continue to shape the field. Residual toxicity and occupational exposure remain central concerns for EtO and, to a lesser extent, liquid chemical sterilants, driving continued regulatory tightening and a search for lower-toxicity alternatives. Cost and infrastructure requirements - particularly capital cost for plasma, VHP and irradiation equipment - can be prohibitive in low-resource settings, where steam autoclaving is likely to remain the dominant modality for the foreseeable future, reinforcing the importance of robust, low-cost steam-sterilization quality assurance in global health contexts. Standardisation across national and international bodies (ISO, AAMI, national regulators) continues to evolve unevenly across emerging technologies, complicating cross-country validation and procurement decisions. Looking forward, promising directions include hybrid and combination-chemistry sterilants designed to shorten cycle times while preserving a non-toxic residue profile; wider adoption of real-time, sensor-based cycle monitoring and biological-indicator alternatives to shorten result turnaround; continued development of supercritical CO₂ and cold-plasma systems toward clinical maturity; and greater attention to the environmental footprint - water and energy use, greenhouse-gas-relevant emissions, and consumable waste - of sterilization technology selection at a health-system level, alongside the traditional efficacy and safety criteria.

CONCLUSION

Surgical instrument sterilization has evolved from a single dominant technology - saturated steam - into a portfolio of complementary conventional and emerging methods, each with a distinct profile of microbicidal mechanism, cycle time, material compatibility, cost and environmental impact. Steam sterilization remains, and is likely to remain, the reference standard for heat- and moisture-stable instrumentation because of its reliability, speed and negligible residue. For the growing category of heat- and moisture-sensitive devices, low-temperature hydrogen-peroxide-based technologies currently offer the most balanced alternative, while ethylene oxide, ionizing radiation, ozone and supercritical carbon dioxide retain important, more specialised roles. No single technology is universally optimal; effective sterile-processing strategy in both hospital and industrial-manufacturing settings depends on maintaining an appropriately matched combination of modalities, underpinned by rigorous validation against international standards and continued monitoring of emerging low-toxicity, rapid-cycle alternatives.

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