REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
1	Rutala WA, Weber DJ; Healthcare Infection Control Practices Advisory Committee. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention. 2008. Updated June 2024. Accessed June 26, 2024. https://www.cdc.gov/infection-control/media/pdfs/Guideline-Disinfection-H.pdf	Guideline	n/a	n/a	n/a	n/a	Provides guidance on the preferred methods for cleaning, disinfection and sterilization of patient care medical devices and for cleaning and disinfecting the healthcare environment.	IVA
2	Rowan NJ, Kremer T, McDonnell G. A review of Spaulding's classification system for effective cleaning, disinfection and sterilization of reusable medical devices: viewed through a modern-day lens that will inform and enable future sustainability. Sci Total Environ. 2023;878:162976.	Literature Review	n/a	n/a	n/a	n/a	This timely review addresses important issues surrounding use of the Spaulding classification system to meet modern-day needs.	VA
3	Rutala WA, Boyce JM, Weber DJ. Disinfection, sterilization and antisepsis: an overview. Am J Infect Control. 2023;51(11S):A3–A12.	Literature Review	n/a	n/a	n/a	n/a	Strict adherence to current disinfection and sterilization guidelines is essential to prevent patient infections and exposures to infectious agents.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
4	Surgical Site Infection Event (SSI). National Healthcare Safety Network. January 2024. Accessed June 26, 2024. https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf	Regulatory	n/a	n/a	n/a	n/a	Provides guidance for standardized SSI definitions and monitoring using NHSN and CPT codes.	n/a
5	Berríos-Torres SI, Umscheid CA, Bratzler DW et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. 2017;152(8):784–791.	Guideline	n/a	n/a	n/a	n/a	Provides guidance on the prevention of surgical site infection. Importance: The human and financial costs of treating surgical site infections (SSIs) are increasing. The number of surgical procedures performed in the United States continues to rise, and surgical patients are initially seen with increasingly complex comorbidities. It is estimated that approximately half of SSIs are deemed preventable using evidence-based strategies.	IVA
6	Guideline for care and cleaning of surgical instruments. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:403–438.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for cleaning surgical instruments, including point-of-use treatment, transport, decontamination, inspection, and general care of reusable medical devices (eg, surgical instruments).	IVA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
7	Guideline for manual high-level disinfection. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:315–338.	Guideline	n/a	n/a	n/a	n/a	Provides guidance to health care personnel for performing safe and effective manual high level disinfection of reusable semicritical items and preventing patient and health care worker injury associated with the handling and use of liquid chemical high-level disinfectants (HLDs).	IVA
8	Guideline for processing flexible endoscopes. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:227–276.	Guideline	n/a	n/a	n/a	n/a	Guidance is provided for processing all types of flexible endoscopes, as well as for controlling and maintaining the environment to support processing activities.	IVA
9	Guideline for sterilization packaging systems. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:593–610.	Guideline	n/a	n/a	n/a	n/a	Provides guidance to perioperative personnel for evaluating, selecting, and using sterilization packaging systems and for packaging the items to be sterilized and subsequently used in operative and other invasive procedures.	IVA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
10	Guideline for design and maintenance of the surgical suite. In: Guidelines for Perioperative Practice AORN, Inc; 2024:79–142.	Guideline	n/a	n/a	n/a	n/a	Provides guidance on the design of the surgical suite; security measures; safety measures during new construction or renovation; planning for utility service interruption; restoration of the surgical suite to full functionality after a utility failure; maintenance of structural surfaces; and design, monitoring, and maintenance of the heating, ventilation, and air conditioning (HVAC) system.	IVA
11	ANSI/AAMI ST79/(R)2022 & 2020 Amendments A1, A2, A3, A4 (Consolidated Text): Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Consensus	n/a	n/a	n/a	n/a	This recommended practice covers steam sterilization in health care facilities. The recommendations are intended to promote sterility assurance and to guide health care personnel in the proper use of processing equipment.	IVC
12	ANSI/AAMI ST8:2013/(R)2018: Hospital Steam Sterilizers. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013.	Consensus	n/a	n/a	n/a	n/a	Provides minimum construction and performance requirements for hospital sterilizers that use saturated steam as the sterilizing agent and have a volume greater than 56.63 liters (2 cubic feet)	IVC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
13	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff. March 2015. Accessed June 26, 2024. US Food & Drug Administration, Center for Devices and Radiological Health. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling	Regulatory	n/a	n/a	n/a	n/a	The focus of this document is to provide guidance to medical device manufacturers in the complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended.	n/a
14	Park CY, Lee JK, Chuck RS. Toxic anterior segment syndrome – an updated review. BMC Ophthalmol. 2018;18(1):276.	Literature Review	n/a	n/a	n/a	n/a	TASS is mostly preventable by the establishment of TASS prevention protocols, regular surgical staff training and thorough adherence to recommendations for cleaning and sterilizing intraocular surgical instruments.	VA
15	Chang DF, Mamalis N; Ophthalmic Instrument Cleaning and Sterilization Task Force. Guidelines for the cleaning and sterilization of intraocular surgical instruments. J Cataract Refract Surg. 2018;44(6):765–773.	Guideline	n/a	n/a	n/a	n/a	These guidelines are intended to assist ASCs in their efforts to adopt appropriate practices for the cleaning and sterilization of intraocular surgical instruments.	IVB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
16	CPG Sec. 300.500 *Reprocessing of Single Use* Devices. US Food & Drug Administration. March 18 , 2005. Accessed June 26, 2024. https://www.fda.gov/media/71769/download#:~:text=Reprocessed%20SUDs%20should%20be%20capable,the%20reprocessors%20to%20be%20reprocessed.	Regulatory	n/a	n/a	n/a	n/a	FDA guidance for reprocessing devices that are labeled or intended for single use.	n/a
17	Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices. Guidance for Industry and FDA Staff. US Food & Drug Administration. May 2006. Accessed June 26, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-section-301-medical-device-user-fee-and-modernization-act-2002-amended-prominent-and#:~:text=On%20October%2026%2C%202002%2C%20section,name%20of%20the%20manufacturer%2C%20a	Regulatory	n/a	n/a	n/a	n/a	FDA guidance for Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
18	Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices. Guidance for Industry and FDA Staff. US Food & Drug Administration. June 2004. Accessed June 26, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-and-modernization-act-2002-validation-data-premarket-notification	Regulatory	n/a	n/a	n/a	n/a	FDA guidance for Medical Device User Fee and Modernization Act of 2002	n/a
19	Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions. US Food & Drug Administration. July 16 , 2003. Accessed June 26, 2024. https://www.fda.gov/files/medical%20devices/published/1427.pdf	Regulatory	n/a	n/a	n/a	n/a	FDA guidance for reprocessing and reuse of single-use devices by third-party and hospital reprocessors.	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
20	Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals. Final Guidance for Industry and FDA. US Food & Drug Administration. July 2001. Accessed June 26, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-recommendations-single-use-devices-reprocessed-third-parties-and-hospitals	Regulatory	n/a	n/a	n/a	n/a	FDA guidance for labeling single-use devices reprocessed by third parties and hospitals.	n/a
21	Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors. Final Guidance for Industry and FDA Staff. US Food & Drug Administration. July 2001. Accessed June 26, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-about-reprocessing-and-reuse-single-use-devices-third-party-and-hospital	Regulatory	n/a	n/a	n/a	n/a	FDA guidance for reprocessing and reuse of single-use devices by third-party and hospital reprocessors.	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
22	21 CFR 807 – Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices Code of Federal Regulations. Accessed June 26, 2024. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807	Regulatory	n/a	n/a	n/a	n/a	The Code of Federal Regulations (CFR) is an annual codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government.	n/a
23	21 CFR 814 – Premarket Approval of Medical Devices Code of Federal Regulations. Accessed June 26, 2024. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-814	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations: procedures for the premarket approval of medical devices intended for human use.	n/a
24	Grantcharov P, Ahmed S, Wac K, Rivas H. Reprocessing and reuse of single-use medical devices: perceptions and concerns of relevant stakeholders toward current practices. Int J Evid Based Healthc. 2019;17(1):53–57.	Nonexperimental	214 participants (patients, physicians, practitioners including OR nurses and staff)	n/a	n/a	Survey	There is a profound lack of awareness of single-use device reprocessing and reuse among all relevant stakeholders. Patients expressed an overwhelming desire for transparency. Despite research and history having shown the practice to be safe, apprehension and misconceptions remain. Survey results suggest that education may be able to subdue such patient concerns.	IIIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
25	Technical Considerations for Additive Manufactured Medical Devices. US Food & Drug Administration. 2017. Accessed June 26, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-additive-manufactured-medical-devices	Regulatory	n/a	n/a	n/a	n/a	FDA guidance for technical considerations for additive manufactured medical devices.	n/a
26	Aguado-Maestro I, De Frutos-Serna M, González-Nava A, Merino-De Santos AB, Garcia-Alonso M. Are the common sterilization methods completely effective for our in-house 3D printed biomodels and surgical guides? Injury. 2021;52(6):1341–1345.	Quasi-experimental	24 cylinders made by 3D printer, Spain	Sterilization by ethylene oxide, gas plasma, and steam	No sterilization	Bacterial culture	High temperatures reached during the procedure of additive manufacturing can decrease the bacterial load of the biomodels. However, there is a potential risk of contamination during the procedure. We recommend sterilization with EtO for in-hospital 3D-printed PLA hollow biomodels or guides. Otherwise, in case of using Gas Plasma, an infill of 100% should be applied. Steam heat completely deformed the cylinders.	IIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
27	Bosc R, Tortolano L, Hersant B et al. Bacteriological and mechanical impact of the Sterrad sterilization method on personalized 3D printed guides for mandibular reconstruction. Sci Rep. 2021;11(1):581.	Quasi-experimental	10 model cutting guides for mandibular reconstruction (oral cancer), 3D printer, France	Sterilization by hydrogen peroxide vapor gas plasma	n/a	Bacterial culture, surface analysis via microscopy, mechanical properties	Personalized surgery is essential to practice, more so in the maxillofacial field where reconstruction has to be as patient specific as possible to gain in symmetry and functionality, allowing a better quality of life. It is feasible to fabricate with the hospital's resources an anatomically accurate patient specific guide by using a low-cost 3D printer and a specific Sterrad sterilization program. This process cannot be extended to other kinds of materials for 3D printers and all new material should be specifically tested.	IIC
28	Chen JV, Tanaka KS, Dang ABC, Dang A. Identifying a commercially-available 3D printing process that minimizes model distortion after annealing and autoclaving and the effect of steam sterilization on mechanical strength. 3D Print Med. 2020;6(1):9.	Quasi-experimental	30mm cubes, 3D printer, United States	Cubes annealed via hot water bath, packaged inside sterilization pouches, and autoclaved via steam sterilization	4 different infill geometries, 7 materials // army-navy retractor designs	Measurements of cubes. Mechanical strength of army-navy retractor designs.	For 30mm cubes, the 3D printing material and infill geometry that deformed the least, respectively, was Essentium PLA and "grid". Hot water-bath annealing results in increased 3D printed model strength, however autoclaving 3D prints markedly diminishes strength. Strength-optimized 3D printed PLA Army-Navy retractors overcome the strength limitation due to autoclaving.	IIC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
29	Keßler A, Dosch M, Reymus M, Folwaczny M. Influence of 3D-printing method, resin material, and sterilization on the accuracy of virtually designed surgical implant guides. J Prosthet Dent. 2022;128(2):196–204.	Quasi-experimental	132 implants placed with digitally designed surgical guides, laboratory, Germany	Various manufacturing techniques (DLA printer, SLA printer, milling) and associated software, printers, and materials; postprocessing	Sterilization by steam 135C for 5 minutes	Accuracy of placement	The specific manufacturing technique, the 3D printing device, the resin material, and the application of preoperative sterilization all affected the accuracy of the postoperative implant position.	IIB
30	Rynio P, Galant K, Wójcik Ł et al. Effects of sterilization methods on different 3D printable materials for templates of physician-modified aortic stent grafts used in vascular surgery – a preliminary study. Int J Mol Sci. 2022;23(7):3539.	Quasi-experimental	3D printed aortic arch template, laboratory, Poland	6 printing materials (PLA, nylon, polypropylene, PETG, resin FDM, resin SLA)	Sterilization by heat (105 C and 121C), hydrogen peroxide plasma, and ethylene oxide	Effectiveness (G stearothermophilis/ B atrophaeus) and deformation	All sterilization protocols were equally effective in destroying microorganisms; however, differences occurred in 3D object deformation. Sterilization at high temperatures deformed aortic templates composed of PLA, PETG, and PP. Plasma and gas sterilization were appropriate for all tested printing materials. Steam autoclaving at 105 C was also effective, which is one of the most popular and cheap methods of sterilization.	IIB
31	Török G, Gombocz P, Bognár E et al. Effects of disinfection and sterilization on the dimensional changes and mechanical properties of 3D printed surgical guides for implant therapy – pilot study. BMC Oral Health. 2020;20(1):19.	Quasi-experimental	15 drill guide templates made from Stratasys Objet MED 610 material, laboratory, Hungary	Disinfection (4% Gigasept), Sterilization plasma, Sterilization autoclave @ 121C for 20min , Sterilization autoclave @134C for 10 min	No sterilization	Surface morphology via scanning electron microscope, length via stereomicroscope, hardness, flexural, compressive strength, x-ray	Plasma sterilization and steam sterilization at 121C were both suitable for sterilizing the tested 3D printed surgical guides	IIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
32	Ferràs-Tarragó J, Sabalza-Baztán O, Sahuquillo-Arce JM et al. Autoclave sterilization of an in-house 3D-printed polylactic acid piece: biological safety and heat-induced deformation. Eur J Trauma Emerg Surg. 2022;48(5):3901–3910.	Quasi-experimental	192 rectangular models made of FFF-PLA, laboratory, Spain	6 different printing protocols were established, each with a different infill percentage.	Sterilization autoclave 134C	Effectiveness (31 common pathogens) and Deformation	The analyzed 3D printing protocol may be applied with any FFF-PLA 3D printer, it is safe and does not significantly alter the morphology of biomodels. These results indicate that 3D printing is associated with significant advantages for health centers as it increases their autonomy, allowing them to easily produce 3D biomodels that can be used for the treatment of fractures.	IIC
33	Ferràs-Tarragó J, Sabalza-Baztán O, Sahuquillo-Arce JM et al. Security of 3D-printed polylactide acid piece sterilization in the operating room: a sterility test. Eur J Trauma Emerg Surg. 2022;48(5):3895–3900.	Quasi-experimental	186 PLA plates, laboratory, Spain	Sterilization autoclave 134C	6 negative controls	Effectiveness (bacteria) and mechanical properties (breaking load, deformation)	This is the first 3D-printing protocol described to print and sterilize 3D biomodels using an autoclave showing its biological safety and its mechanical resistance.	IIC
34	Nack B, Nowakowski E, Nicholson F. A central sterile processing and hospital epidemiology and infection control collaboration to ensure safe patient care. AORN J. 2020;112(1):8–14.	Organizational Experience	Academic medical center, United States	n/a	n/a	n/a	Central Sterile Processing and Hospital Epidemiology and Infection Control partnership is beneficial when addressing the proposed introduction of cutting-edge technology, such as 3D-printed devices.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
35	Guidelines for Design and Construction of Hospitals. The Facility Guidelines Institute; 2022.	Guideline	n/a	n/a	n/a	n/a	Provides guidelines for construction including: minimum recommended program, space, risk assessment, infection prevention, architectural detail, and surface and built-in furnishing needs for clinical and support areas of hospitals, rehabilitation facilities, and ambulatory care facilities. It also addresses minimum engineering design criteria for plumbing, electrical, and heating, ventilation, and air-conditioning (HVAC) systems.	IVC
36	ANSI/AAMI ST58:2013/(R)2018: Chemical Sterilization and High-Level Disinfection in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013.	Consensus	n/a	n/a	n/a	n/a	This recommended practice provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the FDA.	IVC
37	21 CFR 880.6850 Sterilization wrap. Code of Federal Regulations. Accessed June 26, 2024. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-880/subpart-G/section-880.6850	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations: provides identification and classification information for sterilization wrap.	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
38	Cardone A, Grous CA. Relocating sterile processing activities to an off-site facility: cost, design, and project management considerations. AORN J. 2020;112(1):30–38.	Organizational Experience	Academic health system, United States	n/a	n/a	n/a	When considering the option of moving sterile processing activities off-site, facility and department leaders should analyze and evaluate many factors including financial considerations, location options, space requirements, the logistics of transportation, and regulatory stipulations. In addition, leaders should consider risk mitigation plans and ensure surgeon preference cards are accurate.	VA
39	Transporting infectious substances overview. US Department of Transportation: Pipeline and Hazardous Materials Safety Administration. Updated October 17, 2022. Accessed June 26, 2024. https://www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-overview	Regulatory	n/a	n/a	n/a	n/a	Department of Transportation guidance on transporting infectious substances.	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
40	ANSI/AAMI ST40:2004/(R)2018. Table-Top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Health Care Facilities. Artlington, VA: Association for the Advancement of Medical Instrumentation; 2005.	Consensus	n/a	n/a	n/a	n/a	Provides guidelines for dry heat sterilization in health care facilities.	IVC
41	ANSI/AAMI ST41:2008/(R)2018. Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2008.	Consensus	n/a	n/a	n/a	n/a	This recommended practice covers the safe and effective use of ethylene oxide as a sterilant in health care facilities. The provisions of this document are intended to promote sterility assurance, help minimize occupational exposure to ethylene oxide, and guide health care personnel in the proper use of processing equipment.	IVC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
42	Dreikausen L, Blender B, Trifunovic-Koenig M et al. Analysis of microbial contamination during use and reprocessing of surgical instruments and sterile packaging systems. PLoS One. 2023;18(1):e0280595.	Nonexperimental	Environmental Surfaces in the OR, Germany	n/a	n/a	Air sampling, settle plates, contact agar plates	The highest average microbial and particle load was measured in the air of the OR. No microbial load was detected on surgical instruments sampled in the OR. The outer surface of stored sterile packaging systems showed a maximal microbial load of 64 CFU.Compared to properly reprocessed reusable surgical instruments and sterile packaging systems, the air still seems to be the primary potential source of microbial contamination, especially within the OR.	IIIB
43	Rutala WA, Gergen MF, Weber DJ. Does blood on "dirty" instruments interfere with the effectiveness of sterilization technologies? Infect Control Hosp Epidemiol. 2022;43(9):1262–1264.	Quasi-experimental	"Dirty" surgical instruments (uncleaned), laboratory, United States	Instruments inoculated with test organisms with or without blood	Steam sterilization 270C for 4 min, ethylene oxide, hydrogen peroxide gas plasma	Effectiveness (MRSA, VRE, P aeruginosa, M terrae, G stearothermophilus/ B atrophaeus)	Steam sterilization is the most effective sterilization technology with the largest margin of safety, followed by ethylene oxide and hydrogen peroxide gas plasma.	IIB
44	Rutala WA, Gergen MF, Sickbert-Bennett EE, Weber DJ. Comparative evaluation of the microbicidal activity of low-temperature sterilization technologies to steam sterilization. Infect Control Hosp Epidemiol. 2020;41(4):391–395.	Quasi-experimental	Test carriers, laboratory, United States	Carriers inoculated with test organisms in the presence of salt and serum	Sterilization by steam, ethylene oxide, vaporized hydrogen peroxide, hydrogen peroxide gas plasma	Effectiveness (P aeruginosa, E coli, S aureus, VRE, M terrae, C difficile, G stearothermophilus/ B atrophaeus)	Steam sterilization is the most effective and had the largest margin of safety, followed by ETO and HPGP, but VHP showed much less efficacy.	IIA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
45	Zadik Y. Iatrogenic lip and facial burns caused by an overheated surgical instrument. J Calif Dent Assoc. 2008;36(9):689–691.	Case Report	n/a	n/a	n/a	n/a	Case report describing incident where recently sterilized metal instrument caused superficial burn of lip and face during third molar surgery.	VB
46	Nurse 'flash' sterilized surgical equipment: Pt. burned. Case on point: Ford v. Stringfellow Memorial Hospital, 2080567 (10/23/2009)-AL. Nurs Law Regan Rep. 2009;50(7):2.	Case Report	n/a	n/a	n/a	n/a	Legal case in which patient was burned by sterilized wrist traction device that was not cooled before use.	VC
47	Rutala WA, Weber DJ, Chappell KJ. Patient injury from flash-sterilized instruments. Infect Control Hosp Epidemiol. 1999;20(7):458.	Case Report	n/a	n/a	n/a	n/a	Letter to the editor describing incidents of patient burns resulting from instruments sterilized using IUSS.	VB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
48	Roper D, McClean A, Hand CJ. Too hot to handle: how quickly do surgical instruments cool sufficiently to use safely following sterilisation using the Medical Device Decontamination Capability (Forward)?. J R Nav Med Serv. 2018;104(2):87–92.	Quasi-experimental	One light instrument and one heavy instrument, laboratory, austere military setting	Ambient room temperature, pouring 1L sterile water at ambient temperature, pouring 1L cold sterile water, immersing 3L sterile water at ambient temperature 30 seconds, immersing 3L cold sterile water 30 seconds	n/a	Time to achieve safe working temperature range (36.9C to 21C)	The heavy instrument took longer to cool than the light instrument. Immersing the instruments in 3 L of sterile water at ambient room temperature was the fastest and most efficient method (1 minute) to achieve a safe working temperature and was less resource intensive than the pouring methods, which required additional personnel. Immersion in cold water did not result in a time advantage (1 minute) and required the resources of refrigeration to keep the water cold. Ambient room temperature was the longest method (32 minutes) and was not practical for immediate use.	IIC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
49	Tantillo TJ, Stapleton EJ, Frane N et al. The association of immediate-use steam sterilization with the incidence of orthopaedic surgical site infections: a propensity score-matched cohort study. J Bone Joint Surg Am. 2022;104(11):988–994.	Nonexperimental	70,600 patients who underwent orthopedic surgery (ie, total knee arthroplasty, total hip arthroplasty, laminectomy, spinal fusion), 10 hospitals in same system, United States	n/a	n/a	IUSS use and SSI outcomes	IUSS is safe to perform in orthopedic procedures when personnel adhere to the manufacturer's IFU and guidelines for IUSS from AORN and AAMI, such as by complying with protocols for cleaning and decontamination, sterilization, and aseptic transfer; reviewing the IFU for sterilization parameters and verifying that parameters for sterilization were achieved; and logging and tracking IUSS reasons that can be traced to the patient for surveillance.	IIIB
50	Immediate-Use Steam Sterilization. AORN, Inc. 2011. Accessed June 26, 2024. https://www.aorn.org/guidelines-resources/clinical-resources/position-statements	Consensus	n/a	n/a	n/a	n/a	Multisociety statement about IUSS that provides definition of IUSS and basic statements around guiding principles for IUSS practices (competency of staff performing IUSS, IFU related to dry time and appropriate containers for sterilization, aseptic transfer to point of use, FDA clearance of container systems, regulatory surveyor responsibility, process monitoring, instrument inventory adequacy, and quality management).	IVC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
51	Sheffer J. Hospital takes hard look at immediate-use steam sterilization. Biomed Instrum Technol. 2015;49(4):273–276.	Organizational Experience	Hospital, United States	n/a	n/a	n/a	Narrative of organizational experience with IUSS highlighting broken processes in each step including methods for cleaning, and misunderstanding about what constitutes IUSS (described as gravity cycle.)	VB
52	Williams DL, Taylor NB, Epperson RT, Rothberg DL. Flash autoclave settings may influence eradication but not presence of well-established biofilms on orthopaedic implant material. J Orthop Res. 2018;36(5):1543–1550.	Nonexperimental	Titanium metal material, both porous and smooth, from three different manufacturers, laboratory, United States	n/a	Steam sterilization 121C and 132C for 5 minutes and 10 minutes	Effectiveness (MRSA, B subtilis)	Higher temperature (132 C) and increased duration (10 minutes) rendered the biofilms nonviable, but none of the sterilization cycles had the ability the remove the presence of biofilm from the titanium surfaces, either porous or smooth. Sterilization up to 30 minutes did not appear to affect the biofilm's structure or cellular integrity.	IIIB
53	Chang DF, Hurley N, Mamalis N, Whitman J. Evaluation of ophthalmic surgical instrument sterility using short-cycle sterilization for sequential same-day use. Ophthalmology. 2018;125(9):1320–1324.	Quasi-experimental	Phaco handpieces from 3 separate manufacturers, independent medical device validation testing laboratory, United States	Short cycle (unwrapped/ contained, 1min dry time, 3min transit/storage)	Wrapped/contained, full dry cycle, 7-day storage time	Bacterial culture, biologic indicators and controls.	A full drying phase is not necessary when the instruments are kept within the covered sterilizer containment device for prompt use on a sequential case.	IIC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
54	Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings. August 29 , 2014. Accessed June 26, 2024. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-44.pdf	Regulatory	n/a	n/a	n/a	n/a	CMS Memo, Change in terminology regarding Immediate Use Steam Sterilization (IUSS)	n/a
55	van Doornmalen JPCM, Verschueren M, Kopinga K. Penetration of water vapour into narrow channels during steam sterilization processes. J Phys D Appl Phys. 2013;46(6):065201.	Quasi-experimental	Laboratory, Germany	Various lengths of tubing	n/a	Water vapor distribution	Lab simulation studying steam penetration of surfaces in narrow channeled tubes closed at one end (intended to simulate complex lumened medical devices.)	IIA
56	van Wezel RAC, van Doornmalen HW, de Geus J, Rutten S, van Doornmalen Gomez Hoyos JPCM. Second case study on the orientation of phaco hand pieces during steam sterilization. J Hosp Infect. 2016;94(2):194–197.	Quasi-experimental	3 brands of phaco hand pieces, 43 measurements/ Laboratory	Placement of phaco hand pieces at 5 different angles during sterilization	n/a	Temperature and time measurements	The orientation and design of phaco hand pieces are essential factors in achieving sterilization conditions.	IIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
57	van Doornmalen Gomez Hoyos JPCM, van Wezel RAC, van Doornmalen HWJM. Case study on the orientation of phaco hand pieces during steam sterilization processes. J Hosp Infect. 2015;90(1):52–58.	Quasi-experimental	3 brands of phaco hand pieces, 35 measurements/ Laboratory	Pouch-packaged phaco hand pieces oriented in three different ways: vertical with free drainage of open end, horizontal, vertical without free drainage of open end	n/a	Temperature and time measurements	In the investigated combination of sterilizer, process, load, loading pattern and wrapping, phaco hand pieces have to be oriented vertically (upright) with free water drainage to obtain steam sterilization conditions on the inner surface	IIB
58	van Doornmalen JPCM, Tessarolo F, Lapanaitis N et al. A survey to quantify wet loads after steam sterilization processes in healthcare facilities. J Hosp Infect. 2019;103(1):e105–e109.	Qualitative	125 hospital sterilization facilities, Europe	n/a	n/a	Survey	78% percent of facilities recognized wet loads, occurring at frequencies ranging from monthly to every load. Usually, wet loads were identified by the presence of water droplets; these loads were repacked and resterilized. Given the pervasiveness of wet loads, and their impact on reprocessing times and costs, strategies to reduce their frequency are needed.	IIIB
59	Barbosa Rodrigues S, Queiroz de Souza R, Uchikawa Graziano K, Sidnei Erzinger G. Specialists' opinion regarding factors related to wet loads after steam sterilization. J Hosp Infect. 2022;120:117–122.	Nonexperimental	77 steam sterilization specialists from 19 countries, researchers from Brazil	n/a	n/a	Scores on strength of relation of factors associated with wet loads, Delphi technique	The occurrence of wet loads after steam sterilization is multifactorial and depends on the equipment available on the market, in addition to the absence of normative requirements for some factors, such as the rate of steam injection, which may lead to different experiences in practice.	IIIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
60	Sandle T. Ensuring sterility: autoclaves, wet loads, and sterility failures. J GXP Compliance. 2015;19(2):1–10.	Expert Opinion	n/a	n/a	n/a	n/a	Reasons for wet loads including wet steam, inadequate condensate removal, steam traps, pressure control; diagnosing problems with information-gathering strategies/ corrective actions. Corrective actions possibilities: vacuum drying, heating the load before steam introduction, and air in bleed phase, and other approaches. Problems identified may be caused by combination of factors requiring interdisciplinary team to evaluate potential causes.	VC
61	Basu D. Reason behind wet pack after steam sterilization and its consequences: an overview from central sterile supply department of a cancer center in eastern India. J Infect Public Health. 2017;10(2):235–239.	Organizational Experience	Medical center, India	n/a	n/a	n/a	Exploration of wet pack causes and strategies to troubleshoot and prevent wet packs.	VC
62	Seavey R. Troubleshooting failed sterilization loads: process failures and wet packs/loads. Am J Infect Control. 2016;44(5 Suppl):e29–e34.	Expert Opinion	n/a	n/a	n/a	n/a	Practical approach to troubleshooting wet packs and loads.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
63	Fayard C, Lambert C, Guimier-Pingault C, Levast M, Germi R. Assessment of residual moisture and maintenance of sterility in surgical instrument sets after sterilization. Infect Control Hosp Epidemiol. 2015;36(8):990–992.	Quasi-experimental	Laboratory, France	Porcelain carriers in reusable containers with paper filters and wrapped trays.	Positive (package perforated) and negative control (package sealed) per batch	Residual water, bacterial growth	Laboratory study concluding that interrupting the dry cycle on a steam sterilization process does not result in increased microbial contamination after storage of sterilized packages.	IIB
64	Moriya GADA, Graziano KU. Sterility maintenance assessment of moist/wet material after steam sterilization and 30-day storage. Rev Lat Am Enfermagem. 2010;18(4):786–791.	Quasi-experimental	Laboratory, United States	Intentional contamination of packaged porcelain cylinders in laboratory setting, stored at predetermined intervals.	No storage	Bacterial growth (*Serratia marcescens*)	Investigation to test event-related sterility by using deliberate bacterial exposure and 5 predetermined storage durations (14, 28, 90, & 180 days).	IIB
65	List of Lists. Consolidated List of Chemicals Subject to the Emergency Planning and Community Right-To-Know Act (EPCRA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Section 112(r) of the Clean Air Act. US Environmental Protection Agency. Updated May 2024. Accessed June 26, 2024. https://www.epa.gov/system/files/documents/2024-05/epcra-cercla-caa-112r-consolidated-list-of-lists-updated-may-2024_0.pdf	Regulatory	n/a	n/a	n/a	n/a	This consolidated chemical list includes chemicals subject to reporting requirements under the Emergency Planning and Community Right-to Know Act (EPCRA), also known as Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and section 112(r) of the Clean Air Act (CAA).	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
66	Agency for Toxic Substances and Disease Registry. Accessed June 26, 2024. https://www.atsdr.cdc.gov/index.html	Expert Opinion	n/a	n/a	n/a	n/a	ATSDR summary for medical management guidelines for hydrogen peroxide including exposure routes, exposure limits, health effects (acute and chronic) and treatment guidance.	VA
67	IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. Re-evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 71. Lyon, France: World Health Organization International Agency for Research on Cancer; 1999. Accessed June 26, 2024. https://www.ncbi.nlm.nih.gov/books/NBK498701/	Expert Opinion	n/a	n/a	n/a	n/a	Carcinogenic risk monograph published by World Health Organization for Hydrogen Peroxide.	VA
68	Hydrogen Peroxide: TLV Chemical Substances. 7th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists (ACGIH); 2001.	Expert Opinion	n/a	n/a	n/a	n/a	Hydrogen Peroxide - summary of ACGIH maximum average airborne concentration to which a healthy adult worker can be exposed during an 8-hour workday and 40-hour workweek over a lifetime without experiencing adverse health effects. Includes summary of animal and human studies of health effects	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
69	Occupational Chemical Database. Occupational Safety and Health Administration. Accessed June 26, 2024. https://www.osha.gov/chemicaldata/	Regulatory	n/a	n/a	n/a	n/a	Web-based database of OSHA standards and exposure limits for regulated occupational chemicals.	n/a
70	Cornelia R, Warburton PR. Assessing hydrogen peroxide vapor exposure from hospital sterilizers. J Occup Environ Hyg. 2017;14(9):150–157.	Nonexperimental	4 models of hydrogen peroxide sterilizers from 2 manufacturers, 7 hospitals, United States and Canada	n/a	n/a	Hydrogen peroxide concentrations	None of the sterilizers exceeded the OSHA PEL of 1 ppm (8hr time-weighted). However several exceeded the short-term exposure limit (3 ppm) in two states: Washington and Hawaii. One hospital found brief concentrations of 25–40 ppm each time they opened the sterilizer at the end of its cycle. Although not exceeding the OSHA PEL, these exposures are of concern since this concentration is roughly half the NIOSH IDLH of 75 ppm, and operators in a busy hospital environment may receive these exposures multiple times a day.	IIIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
71	Ozone: TLV Chemical Substances. 7th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists (ACGIH); 2001.	Expert Opinion	n/a	n/a	n/a	n/a	Ozone - summary of ACGIH maximum average airborne concentration to which a healthy adult worker can be exposed during an 8-hour workday and 40-hour workweek over a lifetime without experiencing adverse health effects. Includes summary of animal and human studies of health effects.	VA
72	ANSI/AAMI/ISO 11607-1:2019: Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2019.	Consensus	n/a	n/a	n/a	n/a	Specifies the requirements and test methods for materials, performed sterile barrier systems, sterile barrier systems, and packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.	IVC
73	Peracetic Acid: TLV Chemical Substances. 7th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists (ACGIH); 2014.	Expert Opinion	n/a	n/a	n/a	n/a	Peracetic acid - summary of ACGIH maximum average airborne concentration to which a healthy adult worker can be exposed during an 8-hour workday and 40-hour workweek over a lifetime without experiencing adverse health effects. Includes summary of animal and human studies of health effects.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
74	ANSI/AAMI ST108:2023. Water for the Processing of Medical Devices. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2023.	Consensus	n/a	n/a	n/a	n/a	This standard covers the selection and maintenance of effective water quality suitable for processing medical devices.	IVC
75	1,3-Butadiene, Ethylene Oxide and Vinyl Halides (Vinyl Fluoride, Vinyl Chloride and Vinyl Bromide). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol 97. Lyon, France: World Health Organization International Agency for Research on Cancer; 2008. Accessed September 10, 2024. https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/1-3-Butadiene-Ethylene-Oxide-And-Vinyl-Halides-Vinyl-Fluoride-Vinyl-Chloride-And-Vinyl-Bromide--2008	Expert Opinion	n/a	n/a	n/a	n/a	Exposures result form opening the door of the sterilizer and unloading and transferring sterilized material.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
76	Ethylene oxide (ETO): hospitals and healthcare facilities must use a single chamber when sterilizing medical equipment with ETO. Environmental Protection Agency. Updated March 2010. Accessed June 26, 2024. https://archive.epa.gov/pesticides/reregistration/web/html/ethylene_oxide_fs.html	Regulatory	n/a	n/a	n/a	n/a	FDA factsheet listing 2010 rule that EO sterilizers must use a single chamber when sterilizing medical equipment with Ethylene Oxide.	n/a
77	Ethylene oxide (EtO): evidence of carcinogenicity. The National Institute for Occupational Safety and Health. May 1981. Accessed June 26, 2024. https://www.cdc.gov/niosh/docs/81-130/	Expert Opinion	n/a	n/a	n/a	n/a	The National Institute for Occupational Safety and Health (NIOSH) recommends that ethylene oxide be regarded in the workplace as a potential occupational carcinogen, and that appropriate controls be used to reduce worker exposure.	VA
78	Reducing Ethylene Oxide Use. Washington, DC: US Environmental Protection Agency; 2018.	Expert Opinion	n/a	n/a	n/a	n/a	EPA factsheet detailing updates to known EO health hazards and cancer risks and call for health care organizations to choose different modes of sterilization.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
79	Ethelene Oxide: TLV Chemical Substances. 7th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists (ACGIH); 2001.	Expert Opinion	n/a	n/a	n/a	n/a	Ethylene Oxide - summary of ACGIH maximum average airborne concentration to which a healthy adult worker can be exposed during an 8-hour workday and 40-hour workweek over a lifetime without experiencing adverse health effects. Includes summary of animal and human studies of health effects.	VA
80	29 CFR 1910.1047: Ethylene oxide. Code of Federal Regulations. Accessed September 10, 2024. https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-Z/section-1910.1047	Regulatory	n/a	n/a	n/a	n/a	Occupational Safety and Health Standards for Toxic and Hazardous Substances, Ethylene oxide.	n/a
81	Supporting statement for the information collection requirements of the ethylene oxide standard (29CFR1910.1047). Occupational Safety and Health Administration. May 2020. Accessed September 10, 2024. https://downloads.regulations.gov/OSHA-2009-0035-0012/content.pfd	Regulatory	n/a	n/a	n/a	n/a	In-depth discussion of monitoring and data collection for EO exposure monitoring prescribed by OSHA 29CFR1910.1047.	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
82	Seavey RE. Collaboration between perioperative nurses and sterile processing department personnel. AORN J. 2010;91(4):454–462.	Expert Opinion	n/a	n/a	n/a	n/a	Narrative about importance of collaborative relationship between operating room personnel and sterile processing personnel as foundational to providing quality surgical patient care.	VA
83	ANSI/AAMI/ISO 15882:2008/(R)2013: Sterilization of Health Care Products – Chemical Indicators – Guidance for Selection, Use, and Interpretation of Results. Arlington, VA: Association of the Advancement of Medical Instrumentation; 2008.	Consensus	n/a	n/a	n/a	n/a	Guidance for selection, use and interpretation of results for chemical sterilization indicators.	IVC
84	Spear JM, Navarro VB, Gayton L, Reis P. The compliance conversation: navigating variations in sterile processing practices. AORN J. 2021;114(5):430–441.	Expert Opinion	n/a	n/a	n/a	n/a	This article provides an overview of national and international infection prevention and control guidelines, the hierarchical models for organizations to use to update policies at their facilities, and differences in sterilization load release practices inside and outside the United States.	VA
85	Working Party on Improving Parametric Load Release for Steam Sterilization. Improving parametric load release for steam sterilization. J Hosp Infect. 2023;133:49–54.	Nonexperimental	51 steam sterilizers, Europe	n/a	n/a	Sterilization parameters for parametric release	This parametric release method for every load leads to a higher safety for staff and patients in hospitals, a reduction in the use of resources and increased sustainability.	IIIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
86	Koster R, van Wezel RAC, van Doornmalen JPCM. Parametric release with measurements of steam sterilisation parameters: temperature, steam composition and time. Aseptica. 2022;28(1):42–47.	Expert Opinion	n/a	n/a	n/a	n/a	Importance of monitoring physical parameters and use of a sensor to measure non condensing gases in steam.	VA
87	AAMI TIR31:2008: Process Challenge Devices/Test Packs for Use in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2008.	Expert Opinion	n/a	n/a	n/a	n/a	This technical information report provides information that will assist health care facilities in the selection and use of process challenge devices.	VA
88	ANSI/AAMI ST90: 2017: Processing of Health Care Products – Quality Management Systems for Processing in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Consensus	n/a	n/a	n/a	n/a	Provides specifies minimum requirements for quality management systems (QMSs) to effectively, efficiently, and consistently process (transport, clean, decontaminate, disinfect, inspect, package, sterilize, and store) medical devices to prevent adverse patient events and nonmanufacturer-related device failures.	IVC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
89	Weber DJ, Rutala WA. Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. Am J Infect Control. 2013;41(5 Suppl):S67–S71.	Expert Opinion	n/a	n/a	n/a	n/a	Medical devices that enter body tissues should be sterile, whereas devices that contact mucous membranes should be high-level disinfected between patients. Failure to ensure proper cleaning and sterilization or disinfection may lead to patient-to-patient transmission of pathogens. This paper describes a protocol that can guide an institution in managing potential disinfection and sterilization failures.	VA
90	ANSI/AAMI ST55:2016/(R)2023. Table-Top Steam Sterilizers. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2016.	Consensus	n/a	n/a	n/a	n/a	Establishes minimum construction and performance standards for small tabletop steam sterilizers that use saturated steam as the sterilizing agent that have a volume of less than or equal to 56.62 liters (2 cubic feet).	IVC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
91	Sorenson AL, Holland S, Tran K et al. Diffuse lamellar keratitis associated with tabletop autoclave biofilms: case series and review. J Cataract Refract Surg. 2020;46(3):340–349.	Case Report	n/a	n/a	n/a	n/a	Cluster of diffuse lamellar keratitis cases with rates up to 37.2% that only resolved after replacement of the table-top steam sterilizer. A culture of the sterilizer reservoir wall revealed a polymicrobial biofilm of P aeruginosa and B cepacia complex. The facility implemented a cleaning protocol for the new table-top sterilizer that included draining and air drying the reservoir on a regular basis (at the conclusion of usage each week), use of only distilled water, and a boiling water cleaning protocol. After the sterilizer was replaced and the reservoir cleaning protocol was implemented, the incidence of diffuse lamellar keratitis remained below 2.2%.	VA
92	AORN Position Statement on Environmental Responsibility. AORN, Inc. 2020. Accessed June 26, 2024. https://www.aorn.org/guidelines-resources/clinical-resources/position-statements	Position Statement	n/a	n/a	n/a	n/a	The interdisciplinary health care community serves as a steward of the environment by seeking knowledge about climate and health effects and assessing health care work environments for opportunities to reduce waste, conserve natural resources, and prevent exposure to hazardous materials.	IVB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
93	McGain F, Moore G, Black J. Hospital steam sterilizer usage: could we switch off to save electricity and water? . J Health Serv Res Policy. 2016;21(3):166–171.	Organizational Experience	Hospital, Australia	n/a	n/a	n/a	A strategy to switch off idle sterilizers would reduce electricity use by 66MWh and water use by 1004 kl per year, saving 26% electricity use and 13% of water use, resulting in financial savings of AUD$13,867 (UK£6,517) and a reduction in 79 tons of CO2 emissions per year. An alternative switch-off strategy of one sterilizer from 10:00 h onwards and a second from midnight would have saved 30MWh and 456 kl of water.	VB
94	Rizan C, Lillywhite R, Reed M, Bhutta MF. Minimising carbon and financial costs of steam sterilisation and packaging of reusable surgical instruments. Br J Surg. 2022;109(2):200–210.	Nonexperimental	4 steam sterilizers with a capacity of 1250 L, laboratory, United Kingdom	n/a	134C to 137C for 3 minutes	Carbon footprint	Loading efficiency and packaging type were key for reduction of the carbon footprint, with individually packaged instruments having a higher carbon footprint than instruments packaged as part of a set.	IIIB
95	Logan C. Emergency preparedness: strategies for maintaining water supply quality and access for sterile processing. AORN J. 2023;118(2):87–93.	Literature Review	n/a	n/a	n/a	n/a	Health care facilities should have a water management program to address both normal and abnormal water operations and an emergency water supply plan.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
96	Ethylene Oxide (EtO): Understanding OSHA's Exposure Monitoring Requirements. Occupational Safety and Health Administration. 2007. Accessed June 26, 2024. https://osha.gov/sites/default/files/publications/OSHA_ethylene_oxide.pdf	Expert Opinion	n/a	n/a	n/a	n/a	OSHA handbook providing a general overview of EO exposure monitoring requirements.	VA