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. Atlanta, GA: Centers for Disease Control and Prevention; 2008.	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	Procedure-Associated Module: Surgical Site infection (SSI) Event. Atlanta, GA: Centers for Disease Control and Prevention; 2017.	Regulatory	n/a	n/a	n/a	n/a	Provides guidance for standardized SSI definitions and monitoring using NHSN and CPT codes.	n/a
3	Berrios-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
4	Guideline for cleaning and care of surgical instruments. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2018:907-942.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for cleaning and care of surgical instruments.	IVA
5	Guideline for manual chemical high level disinfection. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2018:883-906.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for manual chemical high level disinfection.	IVA
6	Guideline for processing flexible endoscopes. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2018:799-882.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for all aspects of processing flexible endoscopes.	IVA
7	Guideline for selection and use of packaging systems for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2018:943-956.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for selection and use of packaging systems for sterilization.	IVA
8	Design and maintenance of the surgical suite. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2018:e49-e75.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for design and maintenance of the surgical suite.	IVA

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9	Rutala WA, Weber DJ. Sterilization, high-level disinfection, and environmental cleaning. Infect Dis Clin North Am. 2011;25(1):45-76.	Expert Opinion	n/a	n/a	n/a	n/a	Failure to perform proper disinfection and sterilization of medical devices may lead to introduction of pathogens, resulting in infection. New techniques have been developed for achieving high-level disinfection and adequate environmental cleanliness. This article examines new technologies for sterilization and high-level disinfection of critical and semicritical items, respectively, and because semicritical items carry the greatest risk of infection, the authors discuss reprocessing semicritical items such as endoscopes and automated endoscope reprocessors, endocavitary probes, prostate biopsy probes, tonometers, laryngoscopes, and infrared coagulation devices.	VA
10	High-Level Disinfection (HLD) and Sterilization BoosterPak. The Joint Commission. https://www.jointcommission.org/standards_booster_paks/. Accessed July 13, 2018.	Accreditation	n/a	n/a	n/a	n/a	The Joint Commission, High-level disinfection and sterilization boosterpak for healthcare organizations to address areas of noncompliance with IC.02.02.01.	n/a
11	Rutala WA, Weber DJ. Disinfection and sterilization: an overview. Am J Infect Control. 2013;41(5 Suppl):S2-S5.	Expert Opinion	n/a	n/a	n/a	n/a	When properly used, disinfection and sterilization can ensure the safe use of invasive and noninvasive medical devices. Cleaning should always precede high-level disinfection and sterilization.	VA
12	Rutala WA, Weber DJ. Reprocessing semicritical items: current issues and new technologies. Am J Infect Control. 2016;44(5 Suppl):e53-e62.	Expert Opinion	n/a	n/a	n/a	n/a	Semicritical medical devices are defined as items that come into contact with mucous membranes or nonintact skin (eg, gastrointestinal endoscopes, endocavitary probes). Such medical devices minimally require high-level disinfection. Because many of these items are temperature sensitive, low-temperature chemical methods are usually used rather than steam sterilization. Strict adherence to current guidelines is required because more outbreaks have been linked to inadequately cleaned or disinfected endoscopes and other semicritical items undergoing high-level disinfection than any other reusable medical device.	VA

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13	Rutala WA, Weber DJ. New developments in reprocessing semicritical items. Am J Infect Control. 2013;41(5 Suppl):S60-S66.	Expert Opinion	n/a	n/a	n/a	n/a	Semicritical medical devices require minimally high-level disinfection. Because many of these items are temperature sensitive, low-temperature chemical methods must be used rather than steam sterilization. Strict adherence to current guidelines is required because more outbreaks have been linked to inadequately cleaned or disinfected endoscopes undergoing high-level disinfection than any other medical device. Sterilization is preferred when possible because of risk for these devices.	VA
14	McDonnell G, Burke P. Disinfection: is it time to reconsider Spaulding? J Hosp Infect. 2011;78(3):163-170.	Expert Opinion	n/a	n/a	n/a	n/a	Some high-level disinfectants/sterilants are not effective against certain types of viruses and mycobacteria, this should be recognized as they may not be applicable for use in certain (such as semi-critical) clinical applications.	VA
15	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
16	Weber DJ, Rutala WA. Lessons learned from outbreaks and pseudo-outbreaks associated with bronchoscopy. Infect Control Hosp Epidemiol. 2012;33(3):230-234.	Expert Opinion	n/a	n/a	n/a	n/a	Bronchoscopy/adverse effects; Cross Infection/etiology; Disease Outbreaks; Disinfection/methods/standards; Humans; Practice Guidelines as Topic	VA

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17	AAMI TIR12:2010: Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2010.	Guideline	n/a	n/a	n/a	n/a	This technical information report (TIR) covers design considerations that medical device manufacturers should take into account to help ensure that their products can be safely and effectively processed. IT also provides information on decontamination, cleaning, disinfection, and sterilization processes commonly used in health care facilities so that manufacturers can validate reprocessing procedures that can be recommended to and performed adequately in health care facilities. Labeling recommendations and information on applicable regulations are also provided in the TIR, as well as a bibliography and other informative annexes.	IVC
18	AAMI TIR30:2011: A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2011.	Guideline	n/a	n/a	n/a	n/a	This report is intended as a resource for manufacturers of medical devices who must validate the instructions for reprocessing that they include with their devices. In addition to describing available processes, materials, test methods, and acceptance criteria for cleaning medical devices that are labeled by the manufacturer for reuse and reprocessing, the report also discusses some of the underlying problems and challenges associated with validating a cleaning method. Extensive references and a sample cleaning validation outline are also included.	IVC
19	ANSI/AAMI ST8:2013: Hospital Steam Sterilizers. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013:33.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for 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
20	ANSI/AAMI/ISO 17664: Processing of Health Care Products—Information to be Provided by the Medical Device Manufacturer for the Processing of Medical Devices. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Guideline	n/a	n/a	n/a	n/a	Specifies requirements for the information to be provided by the medical device manufacturer for the processing of a medical device that requires cleaning followed by disinfection and/or sterilization to ensure that the device is safe and effective for its intended use.	IVC

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21	Duro M. Manufacturer's written instructions for use: a critical component. AORN J. 2013;97(6):C7-C8.	Expert Opinion	n/a	n/a	n/a	n/a	This expert opinion brief references AAMI and CMS in highlighting the importance of following manufacturer IFU for sterilizing reusable medical devices in the perioperative setting. It focuses on responsibility of the manufacturer to supply complete IFU, facility to obtain and make available IFU to all who reprocess medical devices, and reprocessing staff (in SPD and perioperative staff) who are responsible for reprocessing.	VC
22	Seavey R. High-level disinfection, sterilization, and antisepsis: current issues in reprocessing medical and surgical instruments. Am J Infect Control. 2013;41(5 Suppl):S111-S117.	Expert Opinion	n/a	n/a	n/a	n/a	Article covers current issues facing sterile processing and perioperative professionals regarding reprocessing of medical and surgical instruments including extended cycles, wet packs, and conflicting IFUs.	VA
23	ANSI/AAMI ST79:Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for 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
24	ANSI/AAMI ST58:2013. Chemical Sterilization and High-Level Disinfection in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013.	Guideline	n/a	n/a	n/a	n/a	Provides guidelines for the selection and use of liquid chemical sterilants/high-level disinfectants and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration for use in hospitals and other health care facilities. Included within the scope of this recommended practice are functional and physical design criteria for chemical sterilization and high-level disinfection processing areas; staff qualifications, education, and other personnel considerations; criteria for selecting LCSs/HLDs and gaseous chemical sterilizers; safety and efficacy considerations in the use of LCSs/HLDs and gaseous chemical sterilizers; preparation of devices for processing by chemical sterilization or HLD,; quality control methods; and quality process improvement. Definitions of terms and informative annexes are also provided.	IVC

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25	AAMI; Accreditation Association for Ambulatory Health Care, Inc; AORN, Inc; et al. Immediate-use steam sterilization. 2011. http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Products/ST79_Immediate_Use_Statement.pdf. Accessed July 18, 2018.	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
26	US Department of Health and Human Services, US Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. 2015. US Food and Drug Administration. https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf. Accessed July 18, 2018.	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
27	US Department of Health and Human Services; US Food and Drug Administration, Center for Devices and Radiological Health. Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals. 2000. US Food and Drug Administration. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107172.pdf. Accessed July 18, 2018.	Regulatory	n/a	n/a	n/a	n/a	This document provides guidance to third party and hospital reprocessors about their responsibility as manufacturers engaged in reprocessing devices labeled for single use under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997. Third party and hospital reprocessors of single-use devices are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including premarket submission requirements (Sections 513 and 515 of the Act; 21 Code of Federal Regulations Pars 807 and 814).	n/a

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28	21 CFR 807: Establishment registration and device Listing for manufacturers and initial importers of devices. Electronic Code of Federal Regulations. https://www.ecfr.gov/cgi-bin/text-idx?SID=3efdf3cc98a571f1c17fdeaa6807d423&mc=true&tpl=/ecfrbrowse/Title21/21cfr807_main_02.tpl. Accessed July 18, 2018.	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
29	21 CFR 814: Premarket approval of medical devices. Electronic Code of Federal Regulations. https://www.ecfr.gov/cgi-bin/text-idx?SID=76317c63bf257feaa77b460e5d4ef182&mc=true&node=pt21.8.814&rgn=div5. Accessed July 18, 2018.	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
30	The Facility Guidelines Institute. Guidelines for Design and Construction of Health Care Facilities. Chicago, IL: American Society for Healthcare Engineering of the American Hospital Association; 2010.	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, the latter by incorporating ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities.	IVB
31	Dunkelberg H, Schmelz U. Determination of the efficacy of sterile barrier systems against microbial challenges during transport and storage. Infect Control Hosp Epidemiol. 2009;30(2):179-183.	Nonexperimental	398 peel packages/ Laboratory study	n/a	2 types of peel pouches subjected to periodic atmospheric pressure changes: (1) plastic film side/paper side (2) plastic film side/nonwoven material side	Microbial growth (cfu)	Plastic/paper packaging did not have a sufficient barrier efficacy for the provided transport and storage, but the plastic/nonwoven packages fulfilled the requirements of European standard EN 556-1. The researchers also discussed that sterility is not only an event-related process but also a time-dependent process in regard to porous medical-grade materials. Environmental factors are considered "events" and expiration should be based on a risk assessment that considers the effectiveness of the package barrier properties and unavoidable environmental influences.	IIIA

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32	Wagner T, Scholla MH. Sterile barrier systems: managing changes and revalidations. J Validation Technol. 2013;19(3):1-8.	Expert Opinion	n/a	n/a	n/a	n/a	Reviews guidance from the harmonized medical packaging standard adopted by European Committee for Standardization (CEN) and International Organization for Standardization (ISO) EN ISO 11607, European Notified Bodies, and the US Food and Drug Administration's Center for Devices and Radiological Health (CDRH) on revalidation of packaging.	VB
33	Moriya GA, Souza RQ, Pinto FM, Graziano KU. Periodic sterility assessment of materials stored for up to 6 months at continuous microbial contamination risk: laboratory study. Am J Infect Control. 2012;40(10):1013-1015.	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
34	Shaffer HL, Harnish DA, McDonald M, Vernon RA, Heimbuch BK. Sterility maintenance study: dynamic evaluation of sterilized rigid containers and wrapped instrument trays to prevent bacterial ingress. Am J Infect Control. 2015;43(12):1336-1341.	Quasi-experimental	Laboratory, United States	Wrapped trays	Rigid containers	Bacterial growth	Comparison of rigid and wrapped containers contamination rates.	IIA
35	21 CFR 880.6850: Sterilization wrap. US Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=880.6850. Accessed July 18, 2018.	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations: provides identification and classification information for sterilization wrap.	n/a
36	ANSI/AAMI ST41:2008/(R)2012: Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2012.	Guideline	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
37	ANSI/AAMI ST40:2004/(R)2010: Table-Top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2010.	Guideline	n/a	n/a	n/a	n/a	Provides guidelines for dry heat sterilization in health care facilities.	IVC

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38	Guideline for environmental cleaning. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2018:7-28.	Guideline	n/a	n/a	n/a	n/a	This document provides guidance for environmental cleaning and disinfection in the perioperative practice setting and are based on the highest quality evidence available. The quality of the research investigating environmental cleaning has not yet achieved a level of rigor to thoroughly define and evaluate best practices for environmental cleaning in health care, including the perioperative setting.	IVA
39	Yoon JH, Yoon BC, Lee HL, et al. Comparison of sterilization of reusable endoscopic biopsy forceps by autoclaving and ethylene oxide gas. Dig Dis Sci. 2012;57(2):405-412.	Nonexperimental	61 forceps that had been used at least 20 times from 6 endoscopy centers	n/a	n/a	EM scanning (visualization) and bacterial growth (cultures)	Steam sterilization more effective than EO in sterilizing reusable endoscopic biopsy forceps	IIIC
40	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
41	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
42	van Wezel RAC, van Doornmalen HWJM, de Geus J, Rutten S, van Doornmalen GH. 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
43	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
44	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

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45	Rutala WA, Weber DJ, Chappell KJ. Patient injury from flash-sterilized instruments. Infect Control Hosp Epidemiol. 1999;20(7):458.	Case Report	2 patients, United States	n/a	n/a	n/a	Letter to the editor describing incidents of patient burns resulting from instruments sterilized using IUSS.	VB
46	Sheffer J. Bright ideas: 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
47	Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol. 1999;20(4):250-278; quiz 279-280.	Guideline	n/a	n/a	n/a	n/a	Recommendations for the prevention of surgical site infections (SSIs)	IVA
48	Sandle T. Ensuring sterility: autoclaves, wet loads, and sterility failures. J GXP Compliance. 2015;19(2):9.	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
49	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
50	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
51	Moriya GA, Graziano KU. Sterility maintenance assessment of moist/wet material after steam sterilization and 30-day storage. Rev Lat Am. 2010;18(4):786-791.	Quasi-experimental	40 typical Brazilian sterile barrier systems (perforated boxes without lids, packed in layer of nonwoven cloth covering)	Steam sterilization at 134 degrees C for 4 minutes. No dry. Intentional inoculation of exterior of packages after sterilization	Steam sterilization at 134 degrees C for 4 minutes. Dry time. Intentional inoculation of exterior of packages after sterilization	Growth of serratia marcescens (the microbe used for intentional inoculation)	The presence of moisture in the interior sterile barrier system did not interfere in the maintenance of content-sterility even after 30 days of storage.	IIC

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52	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
53	Wallace CA. New developments in disinfection and sterilization. Am J Infect Control. 2016;44(5 Suppl):e23-e27.	Expert Opinion	n/a	n/a	n/a	n/a	Review of current state of FDA cleared sterilization technology available in the United States January 2012-June 2015.	VB
54	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. 2015. United States Environmental Protection Agency, Office of Solid Waste and Emergency Response. https://www.epa.gov/sites/production/files/2015-03/documents/list_of_lists.pdf. Accessed July 18, 2018.	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
55	Medical management guidelines for hydrogen peroxide (H2O2). Agency for Toxic Substances and Disease Registry. https://www.atsdr.cdc.gov/MMG/MMG.asp?id=304&tid=55. Accessed July 18, 2018.	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
56	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. https://monographs.iarc.fr/wp-content/uploads/2018/06/mono71.pdf. Accessed July 18, 2018.	Expert Opinion	n/a	n/a	n/a	n/a	Carcinogenic risk monograph published by World Health Organization for Hydrogen Peroxide.	VA
57	Hydrogen peroxide. In: Documentation of the Threshold Limit Values & Biological Exposure Indices 7th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists; 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
58	OSHA standards and exposure limits. OSHA Occupational Chemical Database. https://www.osha.gov/chemicaldata/. Updated 2018. Accessed July 18, 2018.	Regulatory	n/a	n/a	n/a	n/a	Web-based database of OSHA standards and exposure limits for regulated occupational chemicals.	n/a

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59	Ozone. In: Documentation of the Threshold Limit Values & Biological Exposure Indices. 7th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists; 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
60	Dufresne S, Richards T. The first dual-sterilant low-temperature sterilization system. Can J Infect Control. 2016;31(3):169-174.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of new technology in sterilization: ozone combined with hydrogen peroxide (STERIZONE® VP4 Sterilizer).	VB
61	ANSI/AAMI/ISO 11607-1:2006/(R)2015: 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; 2015.	Guideline	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.	IVB
62	Summary for System 1E Liquid Chemical Sterilant Processing. 2010. US Food and Drug Administration. https://www.accessdata.fda.gov/cdrh_docs/pdf9/k090036.pdf. Accessed July 18, 2018.	Regulatory	n/a	n/a	n/a	n/a	FDA device information for peracetic acid sterilizer.	n/a
63	Peracetic acid. In: Documentation of the Threshold Limit Values & Biological Exposure Indices. 7th ed. 2014 Suppl. Cincinnati, OH: American Conference of Governmental Industrial Hygienists; 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
64	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; No. 97. Lyon, France: World Health Organization: International Agency for Research on Cancer; 2008. https://monographs.iarc.fr/wp-content/uploads/2018/06/mono97.pdf. Accessed July 18, 2018.	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

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65	Ethylene oxide (ETO): hospitals and healthcare facilities must use a single chamber when sterilizing medical equipment with ETO. 2010. US Environmental Protection Agency. https://archive.epa.gov/pesticides/reregistration/web/html/ethylene_oxide_fs.html. Accessed July 18, 2018.	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
66	Ethylene oxide (EtO): evidence of carcinogenicity. The National Institute for Occupational Safety and Health. https://www.cdc.gov/niosh/docs/81-130/default.html. Published 1981. Updated 2014. Accessed July 18, 2018.	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
67	Environmental Protection Agency. Reducing ethylene oxide use. 2018. Great Lakes Regional Pollution Prevention Roundtable. http://www.glrppr.org/docs/r5-eto-factsheet-revised-feb2018.pdf. Accessed July 18, 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
68	Ethylene oxide. In: Documentation of the Threshold Limit Values & Biological Exposure Indices. 7th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists; 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
69	29 CFR 1910.1047: Ethylene oxide. Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10070. Accessed July 18, 2018.	Regulatory	n/a	n/a	n/a	n/a	Occupational Safety and Health Standards for Toxic and Hazardous Substances, Ethylene oxide.	n/a
70	Supporting statement for the information-collection requirements of the ethylene oxide (EtO) standard (29 CFR 1910.1047). 2000. Occupational Safety and Health Administration. https://www.osha.gov/Reduction_Act/1218-eto.html. Accessed July 18, 2018.	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
71	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

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72	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 for the Advancement of Medical Instrumentation; 2013.	Guideline	n/a	n/a	n/a	n/a	Guidance for selection, use and interpretation of results for chemical sterilization indicators.	IVB
73	AAMI TIR31:2008: Process Challenge Devices/Test Packs for Use in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2008.	Guideline	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.	IVC
74	ANSI/AAMI ST90: Processing of Health Care Products—Quality Management Systems for Processing in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Guideline	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
75	ANSI/AAMI ST8: Hospital Steam Sterilizers. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2008.	Guideline	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)	IVB
76	ANSI/AAMI ST55:2016: Table-Top Steam Sterilizers. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2016.	Guideline	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
77	AORN Position Statement on Environmental Responsibility. AORN, Inc. https://www.aorn.org/guidelines/clinical-resources/position-statements. Published 2014. Accessed July 18, 2018.	Position Statement	n/a	n/a	n/a	n/a	AORN Position Statement about importance of environmental responsibility and the perioperative nurse's role in care of the environment as extension of the concept of patient care.	IVB
78	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

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79	Passut J, Duro M, Berg DS, Seavey R, Swenson D. A roundtable discussion: the many challenges of sterile processing. Biomed Instrum Technol. 2015;49(4):261-267.	Expert Opinion	n/a	n/a	n/a	n/a	Biggest issues facing sterile processing, according to recognized experts in the field are centered around staff training and education, productivity/staffing, lack of resources, increasing complexity of medical devices, endoscope processing, loaner instrument procedures, cutting corners, and lack of preventative maintenance for equipment.	VC
80	Ethylene oxide (EtO): understanding OSHA's exposure monitoring requirements. Occupational Safety and Health Administration. https://www.osha.gov/Publications/ethylene_oxide.html. Published 2007. Accessed July 18, 2018.	Expert Opinion	n/a	n/a	n/a	n/a	OSHA handbook providing a general overview of EO exposure monitoring requirements.	VA