REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
1	Guideline for cleaning and care of surgical instruments. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:401-440.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guidelines for cleaning and care of surgical instruments.	IVA
2	Guideline for manual chemical high-level disinfection. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:315-342.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guidelines for manual high-level disinfection.	IVA
3	Guideline for processing flexible endoscopes. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:199-288.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guidelines for processing of flexible endoscopes.	IVA
4	Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2019:973-1002.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guidelines for sterilization.	IVA
5	uideline for sterile technique. In: Guidelines for Perioperative Practice. Denver, CO: AORN Inc; 2019:931-972.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guidelines for the sterile technique.	IVA
6	Overview of device regulation. US Food and Drug Administration. https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/default.htm. Accessed July 10, 2019.	Regulatory	n/a	n/a	n/a	n/a	FDA website the provides an overview of medical device regulation in the FDA Center for Devices and Radiological Health (CDRH). Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class II and III pursuant to 21 CFR.	n/a
7	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510k]. Guidance for Industry and Food and Drug Administration Staff. US Food and Drug Administration. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k-guidance-industry-and. Published July 28, 2014. Accessed July 10, 2019.	Regulatory	n/a	n/a	n/a	n/a	FDA document that describes 510(k) process for evaluating substantial equivalence in premarket notifications.	n/a
8	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. US Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling. Published March 17, 2015. Accessed July 10, 2019.	Regulatory	n/a	n/a	n/a	n/a	FDA guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices; provides recommendations for the content and review of premarket notification submissions [510(k)], premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, de novo requests and investigational device exemption (IDE) applications concerning the labeling instructions for reprocessing reusable medical devices.	n/a

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9	Premarket approval (PMA). US Food and Drug Administration. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm. Updated May 16, 2019. Accessed July 10, 2019.	Regulatory	n/a	n/a	n/a	n/a	FDA website describing premarket approval requirements.	n/a
10	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.	Consensus	n/a	n/a	n/a	n/a	Consensus document developed by the Steam Sterilization in Hospital Practices Working Group intended for users of steam sterilization in health care facilities as comprehensive guidance for all aspects of steam sterilization use and quality monitoring.	IVC
11	ANSI/AAMI ST77:2013/(R)2018: Containment Devices for Reusable Medical Device Sterilization. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2018.	Consensus	n/a	n/a	n/a	n/a	Consensus standard developed by the AAMI Reusable Sterilization Container Working Group with the objective of providing minimum labeling, safety, performance, and testing requirements for rigid sterilization containers and instrument organizers. Intended readers are manufacturers of rigid containers and instrument organizers.	IVC
12	Rutala WA, Weber DJ. Choosing a sterilization wrap for surgical packs. Infection Control Today. https://www.infectioncontroltoday.com/environmental-hygiene/choosing-sterilization-wrap-surgicalpacks. Published May 1, 2000. Accessed July 10, 2019.	Expert Opinion	n/a	n/a	n/a	n/a	The characteristics of an ideal wrap are well described.	VA
13	Position Paper: Sterile Barrier Systems–Single Use or Reusables. Augsburg, Germany: Sterile Barrier Association; 2017.	Position Statement	n/a	n/a	n/a	n/a	Sterile Barrier Association (Germany) paper comparing single use Sterile Barrier Systems (SBS) with reusable SBS using 8 decision points.	IVC
14	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.	Consensus	n/a	n/a	n/a	n/a	This standard specifies the requirements and test methods for materials, preformed 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
15	ANSI/AAMI/ISO 11607-2:2006/(R)2015: Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2015.	Consensus	n/a	n/a	n/a	n/a	Specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized and maintain sterility to the point of use. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems, and packaging systems.	IVC

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16	Rutala WA, Weber DJ; Healthcare Infection Control Practices Advisory Committee (HICAC). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Centers for Disease Control and Prevention. https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. Updated May 2019. Accessed July 10, 2019.	Guideline	n/a	n/a	n/a	n/a	Evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patient care medical devices and for cleaning and disinfecting the healthcare environment.	IVA
17	Mobley KS, Jackson JB 3rd. A prospective analysis of clinical detection of defective wrapping by operating room staff. Am J Infect Control. 2018;46(7):837-839.	Nonexperimental	20 sterilization wraps with defect (ie, holes) of varying sizes	n/a	n/a	Examiners ability to identify/defects in sterilization wrap using customary methods (holding up to light).	Inspecting sterilization wrap for defects in the operating room may not be a reliable method of identifying holes in sterilization wrap.	IIIB
18	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 setting, United States - 111 rigid containers, 161 wrapped trays	Dynamic bioaerosol test in 6-jet collision nebulizer inoculated with ***M luteus***	n/a	Bacterial ingress in sterilized rigid and wrapped containers	**Rigid:** of 111 tested, 14 (12.6%) had no bacterial ingress; 25 (22.5%) had 1-9 CFU; 52 (46.8%) had 10-99 CFU; 20 (18%) >100 CFU. **Wrapped:** no ingress. Contamination rates of older (5-9 years of use) was greater than newer rigid containers.	IIB
19	AST Standards of Practice for Packaging Material and Preparing Items for Sterilization. Littleton, CO: Association of Surgical Technologists; 2009.	Position Statement	n/a	n/a	n/a	n/a	Association of Surgical Technologists practice recommendations for selection and use of packaging material for sterilization of items.	IVC
20	Doyle PA, Gurses AP, Pronovost PJ. Mastering medical devices for safe use. Am J Med Qual. 2017;32(1):100-102.	Expert Opinion	n/a	n/a	n/a	n/a	Training for safe use of medical devices is in crisis as it is neither effective nor safety-focused. The researchers recommend actions to remedy shortcomings in purchasing and using medical devices. The themes recommended are improvements in purchasing practices, training development and regulation/policy.	VA
21	Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff. US Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices. Published February 2016. Accessed July 10, 2019.	Regulatory	n/a	n/a	n/a	n/a	FDA guidance document that recommends that manufacturers follow human factors or usability engineering processes during the development of new medical devices, focusing specifically on the user interface, where the user interface includes all points of interaction between the product and the user(s). The goal is to ensure that the device user interface has been designed such that use errors that occur during use of the device that could cause harm or degrade medical treatment are either eliminated or reduced to the extent possible.	n/a

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22	Final Guidance on Environmentally Preferable Purchasing. US Environmental Protection Agency. https://www.epa.gov/sites/production/files/2015-09/documents/finaleppguidance.pdf. Published August 1999. Accessed July 10, 2019.	Regulatory	n/a	n/a	n/a	n/a	Government guidance for Executive Order (EO) 13101 entitled "Greening the Government through Waste Prevention, Recycling and Federal Acquisition."	n/a
23	Spruce L. Back to basics: packaging systems. AORN J. 2018;107(5):602-610.	Expert Opinion	n/a	n/a	n/a	n/a	Packaging instruments correctly facilitates proper sterilization of contents. Multiple packaging systems are available and perioperative personnel should consider use life, durability, and ease of use of each when selecting products.	VA
24	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	Increasing complexity in invasive procedures has resulted in increasing complexity in medical device design and handling. Users should follow current evidence-based practices and be aware of updates in packaging and ensure instrument sets weigh no more than 25 pounds.	VA
25	Brusco J, Ogg M. Health care waste management and environmentally preferable purchasing. AORN J. 2010;92(Suppl 6):S62-S69.	Expert Opinion	n/a	n/a	n/a	n/a	Offers resources and strategies for environmentally-responsible hospital purchasing.	VB
26	Conrardy J, Hillanbrand M, Myers S, Nussbaum GF. Reducing medical waste. AORN J. 2010;91(6):711-721.	Organizational Experience	Regulated medical waste from 12 surgical services in 2 hospitals	n/a	n/a	n/a	Organizational experience project evaluating the effects of using reusable surgical basins, gowns, table/mayo stand covers in place of disposable products.	VA
27	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	10 steam sterilized packages with 1 minute dry time; 5 rigid containers, 5 wrapped	Rigid and wrapped containers stored for 0, 1, 3, 7, and 14 days	Positive control for each packaging method and storage period	Microbial growth on porcelain carriers & residual water samples	Residual moisture in packages showed no growth in retained moisture in either packaging type at all storage time periods; results of this study suggest that wet packs/loads remain uncontaminated during storage.	IIB
28	Puangsa-Ard Y, Thaweboon S, Jantaratnotai N, Pachimsawat P. Effects of resterilization and storage time on sterility of paper/plastic pouches. Eur J Dent. 2018;12(3):417-421.	Quasi-experimental	6720 paper/plastic pouches in 4 experimental groups	Filter paper placed inside each pouch, which was sealed, sterilized and stored for up to 6 months	Positive control	Bacterial growth	In a closed storage condition, the paper/plastic pouches passed multiple sterilization processes (up to 5 sterilization cycles). All experimental specimens showed no bacterial growth.	IIB
29	Diab-Elschahawi M, Blacky A, Bachhofner N, Koller W. Challenging the Sterrad 100NX sterilizer with different carrier materials and wrappings under experimental "clean" and "dirty" conditions. Am J Infect Control. 2010;38(10):806-810.	Quasi-experimental	90 samples	Tested the sporicidal effect of the sterilizer (hydrogen peroxide vapor) on the carrier materials titanium, polyurethane with single versus 3 wrappings of inoculated carriers with clean and contaminated (inoculated with organic and inorganic burdens) conditions.	Biological indicator	Biological indicator results	Qualitative results show that irrespective of number of wrappings in the clean condition, sterilization effectiveness was equal on all three carrier materials. Any organic or inorganic challenge significantly impaired the sterilization outcome. Thorough and reliable cleaning of medical devices prior to sterilization with hydrogen peroxide vapor systems is of upmost importance.	IIB

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30	Guideline for medical device and product evaluation. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:715-724.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guidelines for the medical device and product evaluation.	IVA
31	Herman P, Larsen C. Measuring porous microbial barriers, part 1. Medical Device and Diagnostic Industry. https://www.mddionline.com/measuring-porous-microbial-barriers-part-1. Published May 1, 2008. Accessed July 10, 2019.	Position Statement	n/a	n/a	n/a	n/a	Discussion of ASTM International microbial barrier test for sterilized packaging including filtration theory (interception, inertial impaction, diffusion) and the Barrier Test Consortium Project.	IVA
32	Herman P, Larsen C. Measuring porous microbial barriers, part 2. Medical Device and Diagnostic Industry. https://www.mddionline.com/measuring-porous-microbial-barriers-part-2. Published June 1, 2008. Accessed July 10, 2019.	Position Statement	n/a	n/a	n/a	n/a	Covers the development of ASTM F2638-07 and provides a comparison of microbial test methods versus ASTM F1608 (the log reduction value test). Aerosol filtration required to perform test is included.	IVA
33	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.	Consensus	n/a	n/a	n/a	n/a	Technical information report (TIR) developed to assist medical device manufacturers in the design, testing, and labeling of devices intended for reuse and reprocessing in health care facilities. Document can also be used by health care professionals as a resource for identifying the questions they should ask manufacturers when considering a product for purchase or a product currently in use.	IVC
34	Wagner T, Scholla MH. Sterile barrier systems: managing changes and revalidations. Journal of Validation Technology. 2013;19(3):1-8.	Literature Review	n/a	n/a	n/a	n/a	This paper 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 and Drug Administration's Center for Devices and Radiological Health (CDRH) on revalidation of packaging. Based on these guidelines, potential changes to the package and packaging process are categorized and reviewed.	VA
35	Laustsen G. Reduce--recycle--reuse: guidelines for promoting perioperative waste management. AORN J. 2007;85(4):717-728.	Expert Opinion	n/a	n/a	n/a	n/a	Expert opinion article that outlines historical perspectives on environmental sustainability in health care, case vignette, suggestions for perioperative greening, and benefits of green nursing.	VA
36	AORN position statement on environmental responsibility. AORN, Inc. https://www.aorn.org/guidelines/clinical-resources/position-statements. Revised 2014. Accessed July 10, 2019.	Position Statement	n/a	n/a	n/a	n/a	AORN position statement outlining nurses' responsibility to advocate for patients' health by protecting the environment in which patients live; advocates for environmentally responsible practices in the operating room.	IVB

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37	Lee RJ, Mears SC. Greening of orthopedic surgery. Orthopedics. 2012;35(6):e940-e944.	Organizational Experience	One hospital switched to rigid sterilization containers from polypropylene wrap	n/a	n/a	n/a	Researchers conducted an improvement project in one organization to evaluate efforts to decrease waste in orthopedic surgery using recommendations from Practice Greenhealth group: "Greening the OR." "Blue wrap" cost decrease after intervention by 70% with additional savings in reprocessing after wrap failure and waste cost for those wraps that were sent as "regulated waste tonnage."	VA
38	Krohn M, Fengler J, Mickley T, Flessa S. Analysis of processes and costs of alternative packaging options of sterile goods in hospitals—a case study in two German hospitals. Health Econ Rev. 2019;9(1):1.	Organizational Experience	Comprehensive analysis of actual cost of use for sterilization wrap and rigid containers in multiple configurations	n/a	n/a	n/a	Cost analysis of different sterilization container/wrap methods in Germany: sterilization container without inner wrap, one-step sterilization wrap, and two sheets sterilization wrap.	VB
39	ANSI/AAMI ST58:2013: 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	Consensus standard intended for users of chemical sterilants in health care settings for the safe use of chemical sterilants including workplace safety information, vaporing monitoring, product testing, personnel training and quality process recommendations.	IVC
40	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; 2018.	Consensus	n/a	n/a	n/a	n/a	Consensus standard developed by the AAMI Ethylene Oxide Sterilization Hospital Practices working group intended to help assure achievement of sterilization with EO sterilizers, maintenance of sterility until point of use, and reduction of occupational exposure to EO.	IVC
41	ANSI/AAMI ST65:2008/(R)2018: Processing of Reusable Surgical Textiles for Use in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2018.	Consensus	n/a	n/a	n/a	n/a	Recommended practice that provides guidelines for the proper handling, processing, and preparation of reusable surgical textiles either on-site or off-site for use in health care facilities. Specifically addresses design criteria for functional work areas; staff qualifications, education, training, dress codes, and other personnel considerations; receiving and handling of soiled surgical textiles; laundry processing considerations; transport of both soiled and clean surgical textiles.	IVC
42	Larrick K; AAMI. Examining the new AAMI standard . . . containment devices for reusable medical device sterilization. Biomed Instrum Technol. 2007;41(2):155-156.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of ANSI/AAMI ST77:2006, the first US performance standard for rigid sterilization container systems and other containment devices.	VA

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43	Luqueta GR, Santos ED 2nd, Pessoa RS, Maciel HS. Evaluation of disposable medical device packaging materials under ozone sterilization. Res Biomed Eng. 2017;33(1):58-68.	Qualitative	Four types of packaging evaluated in ozone-containing sterilization including paper-plastic, Tyvek-plastic, SMS, crepe paper.	n/a	n/a	Qualitative differences in packaging color, appearance, and tactile of each material using attenuated total reflection spectrometer at resolution of 2 cm-1	Results suggest that medical grade paper-plastic pouch is the most appropriate disposable medical device packaging to be sterilized by ozone when compared to other materials.	IIIB
44	Room design. In: HVAC Design Manual for Hospitals and Clinics. 2nd ed. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE); 2013:151-202.	Guideline	n/a	n/a	n/a	n/a	HVAC design manual for hospitals and clinics. Section 8.9 includes specific guidance for central sterile departments, which are designated as a critical area, composed of three main sections: dirty, clean, and sterile. Packaging occurs in the clean area.	IVC
45	Guidelines for Design and Construction of Hospitals. St Louis, MO: Facility Guidelines Institute; 2018.	Guideline	n/a	n/a	n/a	n/a	Hospital Guidelines requirements provide minimum design standards for general hospitals, freestanding emergency facilities, critical access hospitals, psychiatric hospitals, rehabilitation hospitals, children's hospitals, and mobile/transportable medical units.	IVC
46	Veiga-Malta I. Preventing healthcare-associated infections by monitoring the cleanliness of medical devices and other critical points in a sterilization service. Biomed Instrum Technol. 2016;50(Suppl 3):45-52.	Quasi-experimental	80 surgical instruments, and environmental/worker hands assessment over one month	Processing instruments in a washer-disinfector of surgical instruments	Manual cleaning	ATP and residual protein test	This study analyzed the cleanliness of surgical instruments, work surfaces, and hands of workers in an instrument processing department.	IIB
47	Standards FAQ details. Temperature and humidity—monitoring requirements for sterile supply storage areas. The Joint Commission. https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=1686. Accessed July 10, 2019.	Regulatory	n/a	n/a	n/a	n/a	The Joint Commission statement on monitoring temperature and humidity in sterile supply areas. Organizations should determine the appropriate temperature and humidity (and ventilation) parameters based on the design criteria at the time of construction. References ASHRAE, NFPA, and FGI.	n/a
48	Guideline for design and maintenance of the surgical suite. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:73-104.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guidelines for the design and maintenance of the surgical suite. Addresses environment of care recommendations.	IVA

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49	Guidelines for Design and Construction of Outpatient Facilities. St Louis, MO: Facility Guidelines Institute; 2018.	Guideline	n/a	n/a	n/a	n/a	Outpatient Guidelines provides minimum design standards for a variety of outpatient facility types, including facilities for general and specialty medical services facilities, outpatient imaging, urgent care, outpatient surgery, emergency services, endoscopy, renal dialysis, outpatient psychiatric services, outpatient rehabilitation services, and general dentistry as well as birth centers, infusion centers, and mobile/transportable medical units.	IVC
50	Take these steps to avoid issues with instruments. Same Day Surg. 2016;40(11):124-126.	Expert Opinion	n/a	n/a	n/a	n/a	Author is a surveyor for AAAHC and recommends 7 steps to avoid instrument issues in ambulatory care setting	VA
51	Blackmore CC, Bishop R, Luker S, Williams BL. Applying lean methods to improve quality and safety in surgical sterile instrument processing. Jt Comm J Qual Patient Saf. 2013;39(3):99-105.	Organizational Experience	At Virginia Mason Medical Center (Seattle), a quality improvement project over 37 months	n/a	n/a	n/a	Improvement project using a quality monitoring approach at Virginia Mason Medical Center in Seattle, WA. Lean methods were employed through redefining operator roles in sterile processing, alteration of the workspace, mistake-proofing, quality monitoring, staff training, and continuous feedback; processing errors decreased over 37-month time period. Instrument processing errors are amenable to substantial improvement using Lean techniques.	VA
52	Sonstelie A, Dorval D, Pfeifer S. Bringing order to sterile processing through standardized processes. Biomed Instrum Technol. 2016;Spring(Suppl):29-31.	Expert Opinion	n/a	n/a	n/a	n/a	Standardizing work practices can be a long and arduous task, but it is worth the investment.	VA
53	Stockert EW, Langerman A. Assessing the magnitude and costs of intraoperative inefficiencies attributable to surgical instrument trays. J Am Coll Surg. 2014;219(4):646-655.	Organizational Experience	Observation of 49 procedures and 237 trays, evaluating average instrument use rates for 4 specialties.	n/a	n/a	n/a	The researchers sought to quantify the percent use of instruments used per instrument tray in a single institution among 4 specialties. Cost of processing instruments was estimated through time observation and calculation of personnel wages. Study demonstrates that in this organization, the percent use of instruments across surgical specialties and multiple trays are low. Attention to tray composition, and efforts to reduce the number of unused instruments may result in cost savings.	VA

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54	Cuny E, Collins FM. Instrument processing, work flow and sterility assurance. RDH. 2013;33(6):69-77.	Expert Opinion	n/a	n/a	n/a	n/a	Following regulations and occupational safety standards are important in processing dental instruments including preparation, cleaning, and packaging items for sterilization. Use of organizing cassettes can limit risk of exposure injuries for the operator while simplifying and streamlining the process.	VB
55	Kohn WJ, Collins AS, Cleveland JL, Harte JA, Eklund KJ, Malvitz DM; Centers for Disease Control and Prevention (CDC). Guidelines for infection control in dental health-care settings—2003. MMWR Recomm Rep. 2003;52(RR-17):1-61.	Guideline	n/a	n/a	n/a	n/a	Recommendations are provided regarding 1) educating and protecting dental health-care personnel; 2) preventing transmission of bloodborne pathogens; 3) hand hygiene; 4) personal protective equipment; 5) contact dermatitis and latex hypersensitivity; 6) sterilization and disinfection of patient-care items; 7) environmental infection control; 8) dental unit waterlines, biofilm, and water quality; and 9) special considerations (e.g., dental handpieces and other devices, radiology, parenteral medications, oral surgical procedures, and dental laboratories).	IVA
56	Guideline for prevention of retained surgical items. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:765-814.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guideline for the prevention of retained surgical items.	IVA
57	Costa DM, Lopes LKO, Tipple AFV, et al. Effect of hand hygiene and glove use on cleanliness of reusable surgical instruments. J Hosp Infect. 2017;97(4):348-352.	Quasi-experimental	45 halstead mosquito forceps	5 groups handled instruments with: 1) nitrile gloved hands, 2) clean bare hands (immediately following hand hygiene), 3) bare hands 1 hour after hand hygiene, 4) bare hands 2 hours after hand hygiene, 5) bare hands 4 hours after hand hygiene	See intervention	Halsted-mosquito forceps were assessed for adenosine triphosphate (ATP), protein and microbial contamination after handling with gloved and ungloved but washed hands using an ATP surface swab test, bicinchoninic acid assay, and standard culture plate/broth, respectively.	Instrument inspection, assembling, lubricating and packing should be performed using either gloves or within 1 h of washing hands.	IIA

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58	Trier T, Bello N, Bush TR, Bix L. The role of packaging size on contamination rates during simulated presentation to a sterile field. Plos One. 2014;9(7):e100414.	Nonexperimental	Recruited 97 subjects at three locations (58th AORN Conference, 2011 AST annual meeting, and at Pontiac Regional Medical Center)	n/a	n/a	Evaluated healthcare worker hand contact with package contents relative to package size	Results of this work indicate that increased contamination rates are associated with larger pouches when compared to smaller pouches. The results add to a growing body of research which investigate packaging's role in serving as a pathway for product contamination during aseptic presentation. Future work should investigate other packaging design factors (e.g. material, rigidity, and closure systems) and their role in contamination.	IIIB
59	Papaioannou A. A review of sterilization, packaging and storage considerations for orthodontic pliers. Int J Orthod Milwaukee. 2013;24(3):19-21.	Literature Review	n/a	n/a	n/a	n/a	Discussion of specific packaging methods for orthodontic pliers in dental practices; only 2 methods meet guidelines: 1) wrapped cassettes with compression arms or railings and 2) v-shaped orthodontic sterilization pouches.	VC
60	Guideline for safe patient handling and movement. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2019:817-868.	Guideline	n/a	n/a	n/a	n/a	Evidence-based AORN guidelines for safe patient handling and movement.	IVA
61	. Lucas AD, Chobin N, Conner R, et al. Steam sterilization and internal count sheets: assessing the potential for cytotoxicity. AORN J. 2009;89(3):521-531.	Quasi-experimental	4 sets of 5 different instruments	Steam sterilization of instruments in contact with paper with ink of different types	Identical instruments sterilized in the same way with no labels (no exposure to paper with ink)	Cytotoxity upon exposure to paper with ink	The project provides preliminary information to suggest that label and toner ink transferred during steam sterilization is not cytotoxic; however, further research is needed.	IIA
62	ANSI/AAMI/ISO 11140-1:2014: Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2014.	Consensus	n/a	n/a	n/a	n/a	Standard that specifies performance requirements for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances.	IVC
63	Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care. Version 2.2. Atlanta, GA: Centers for Disease Control and Prevention; 2015.	Guideline	n/a	n/a	n/a	n/a	A summary guide of infection prevention recommendations for outpatient (ambulatory care) settings.	IVA
64	Waked WR, Simpson AK, Miller CP, Magit DP, Grauer JN. Sterilization wrap inspections do not adequately evaluate instrument sterility. Clin Orthop Relat Res. 2007;462:207-211.	Quasi-experimental	50 surgical sterilization wraps inspected by personnel	40 wraps with varying sizes of puncture defects	10 wraps with no defects	1. visual detection rate of different sizes of defects in sterilization wraps; 2. bacterial contamination with each puncture defect size	Researchers found that substantial perforations in sterilization wraps frequently are missed when evaluated with commonly-used techniques. Defects the diameter of a pencil (6.7mm) were missed 18% of the time. Results raise questions about effectiveness of visualization as a screening method for defects.	IIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
65	Webster J, Radke E, George N, Faoagali J, Harris M. Barrier properties and cost implications of a single versus a double wrap for storing sterile instrument packs. Am J Infect Control. 2005;33(6):348-352.	Quasi-experimental	1199 trays	Single versus double wrap for steam sterilization	Control: biological testing of items cleaned but not sterilized	Microbial growth	The researchers concluded that contamination rates of single-wrapped versus double-wrapped steam sterilized trays were not significantly significant; suggested cost and time savings could be achieved by converting practice to single wrap using new (in 2005) single step double ply wrap.	IIC
66	Program: Ambulatory. HR.01.05.03: Staff participate in ongoing education and training. In: The Joint Commission Comprehensive Accreditation and Certification Manual. E-dition. Oakbrook Terrace, IL: The Joint Commission; 2018.	Regulatory	n/a	n/a	n/a	n/a	Requirements for staff education and training for accredited ambulatory facilities.	n/a
67	State Operations Manual Appendix L—Guidance for Surveyors: Ambulatory Surgical Centers. Rev 137; 2015. Centers for Medicare & Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_l_ambulatory.pdf. Accessed July 10, 2019.	Accreditation	n/a	n/a	n/a	n/a	Surveyor guidance for Ambulatory Surgical Center Surveys to determine compliance with the Federal requirements set forth in the Medicare Conditions for Coverage (CfC) in order to receive Medicare/Medicaid payment.	n/a
68	State Operations Manual Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Rev 183; 2017. Centers for Medicare & Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf. Accessed July 10, 2019.	Accreditation	n/a	n/a	n/a	n/a	Provides accreditation information for hospitals for survey to determine compliance with the Medicare Conditions of Participation (CoP) set forth at 42 CFR Part 482.	n/a
69	Clinical records and health information. In: Accreditation Handbook for Ambulatory Health Care. Skokie, IL: Accreditation Association for Ambulatory Health Care, Inc; 2018:61-66.	Accreditation	n/a	n/a	n/a	n/a	Handbook intended to serve as resource for accreditation for ambulatory surgery centers and for organizations that own and operate at least 10 sites of nonsurgical care and seek accreditation as a network. The standards are intended to provide organizations with a patient-centered approach to ensuring quality and patient safety.	n/a
70	Personnel: knowledge, skill & CME training. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14.5. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2018:76-77.	Regulatory	n/a	n/a	n/a	n/a	Details required knowledge, skill, and CME training for personnel in an accredited outpatient surgical facility.	n/a
71	Gould DJ, Hale R, Waters E, Allen D. Promoting health workers' ownership of infection prevention and control: using normalization process theory as an interpretive framework. J Hosp Infect. 2016;94(4):373-380.	Qualitative	20 informants in one institution (purposive sampling of employees)	n/a	n/a	Open-ended questions, opening question asked informants to explain what "ownership of infection prevention and control" means in their work	Six themes emerged: 1) ability to make a sense of ownership 2) always being vigilant, 3) importance of access to information, and 4) being able to learn together in a no-blame culture.	IIIC

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72	Are staff pressured on sterilization? Intervene, or risk device compromise. Same Day Surg. 2012;36(5):49-51.	Expert Opinion	n/a	n/a	n/a	n/a	Planning for instrument turnover, hiring experienced personnel, requiring sterile processing certification, and ensuring that an adequate number of instruments are on hand are key in preventing problems in sterile processing departments.	VA
73	Benner P. From Novice to Expert: Excellence and Power in Clinical Nursing Practice. Upper Saddle River, NJ: Prentice Hall Health; 2001.	Expert Opinion	n/a	n/a	n/a	n/a	Presents a model of nursing practice describing five levels of competency. Each level is described in the words of nurses who were interviewed and observed individually and in small groups, in patient care situations where the nurse made a positive difference in patient outcome. Asserts that perceptual awareness is central to good nursing judgement and that this begins with intuition followed by critical analysis. Discussion encompasses the helping role, the phenomenon of caring, management of rapidly changing situations, and collaborative relationships.	VA
74	ANSI/AAMI ST91:2015: Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2015.	Consensus	n/a	n/a	n/a	n/a	Provides guidelines for precleaning, leak-testing, cleaning, packaging (where indicated), storage, high-level disinfecting, and/or sterilizing of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, surgical flexible endoscopes (e.g., flexible ureteroscopes), and semi-rigid operative endoscopes (e.g., choledochoscopes) in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these devices and accessories.	IVC
75	Swenson D. Why benchmarking is important to sterile processing. Biomed Instrum Technol. 2016;50(2):117-120.	Expert Opinion	n/a	n/a	n/a	n/a	Organizations should benchmark either internally or externally for improvement	VA
76	Surgical services (SS). In: NIAHO: National Integrated Accreditation for Healthcare Organizations: Interpretive Guidelines and Surveyor Guidance. Version 11. Milford, OH: DNV GL Healthcare USA, Inc; 2014:80-91.	Accreditation	n/a	n/a	n/a	n/a	"verify that there is a process in place for sterilized materials and that these materials are packaged, labeled and stored in a manner that ensures sterility"	n/a

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77	Seavey RE. Sterile processing accreditation surveys: risk reduction and process improvement. AORN J. 2015;102(4):358-368.	Expert Opinion	n/a	n/a	n/a	n/a	Expert recommendations for accreditation survey readiness for all healthcare settings that perform sterile processing for the purpose of reducing risk to patients and personnel, promote best practices, and improve patient care.	VA
78	Knudson L. Identifying and eliminating sources of wet packs. AORN J. 2014;99(4):C1, C9-10.	Expert Opinion	n/a	n/a	n/a	n/a	Health care personnel should follow sterilization and packaging guidelines established by national organizations and adhere to manufacturers instructions for use for cleaning, packaging, and sterilizing items to achieve sterility. A wet pack should be considered contaminated and root cause analysis should be performed by an interdisciplinary team.	VA
79	IAHCSMM position paper on the management of loaner instrumentation. International Association of Healthcare Central Service Materiel Management. https://www.iahcsmm.org/images/Resources/Loaner_Instrument/Position-Paper.pdf. Accessed July 10, 2019.	Position Statement	n/a	n/a	n/a	n/a	IAHCSMM position paper on loaner instrumentation. Provides recommendations for what a loaner instrument program should include, and provides a checklist	IVA
80	Prince D, Mastej J, Hoverman I, Chatterjee R, Easton D, Behzad D. Challenges to validation of a complex nonsterile medical device tray. Biomed Instrum Technol. 2014;48(4):306-311.	Quasi-experimental	14 trays	1) Sterilized packaged in either rigid container or wrapped and 2) Sterilized in a minimally versus maximally loaded chamber	See intervention	Temperature mapping in sterilizer chamber and biological indicator result within packaging system	Critical sterilization parameters are not singular. Critical parameters are tray design, instrument selection and location, density within the tray system, and tray system weight. This study reports how chamber load and rigid containers are strong influencers of sterilization effectiveness	IIB
81	Standards of perioperative nursing. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:693-708.	Position Statement	n/a	n/a	n/a	n/a	The standards of perioperative nursing focus on the process of providing nursing care and performing professional role activities. These standards apply to all nurses in the perioperative setting and were developed by AORN using the American Nurses Association's (ANA) scope and standards of practice for nursing and nursing administration as the foundation.	IVB