REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
1	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
2	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
3	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
4	Guideline for sterilization. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:997–1024.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for sterilizing reusable medical devices to be used in perioperative and procedural settings.	IVA
5	Guideline for sterile technique. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:959–996.	Guideline	n/a	n/a	n/a	n/a	Provides guidance on the principles and processes of sterile technique.	IVA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
6	Overview of device regulation. US Food & Drug Administration. Accessed August 13, 2024. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation	Regulatory	n/a	n/a	n/a	n/a	FDA overview of device regulation.	n/a
7	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [501(k)]. US Food & Drug Administration. July 28 , 2014. Accessed August 13, 2024.	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. 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	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

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
9	ANSI/AAMI ST79:2017/(R)2022 w/ AMDs A1:2020, A2:2020, A3:2020, A4:2020: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Association for the Advancement of Medical Instrumentation; 2023.	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
10	ANSI/AAMI ST77:2013/(R)2018: Containment Devices for Reusable Medical Device Sterilization. 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
11	ANSI/AAMI/ISO 11607-1:2019/A1:2023: Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems. 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

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
12	ANSI/AAMI/ISO 11607-2:2019/A1:2023. Packaging for Terminally Sterilized Medical Devices. Part 2: Validation Requirements for Forming, Sealing and Assembly Processes. Association for the Advancement of Medical Instrumentation; 2024.	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
13	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
14	Vocelle AR, Trier T, Bix L, Bush TR. A method for quantifying key components of the opening process for opening pouch-style packages containing medical devices. Appl Ergon. 1219;76:97–104.	Nonexperimental	11 parameters for opening pouch style packages tested with 9 health care professionals	n/a	n/a	Handling time, package manipulations, pulls, pull distance, times spent pulling	All nine people crossed above the sterile field when opening packages. Opening large packages result in more time spent over the sterile field.	IIIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
15	Perez P, Bush TR, Hong HG, Pan W, Miller L, Bix L. Reducing levels of medical device contamination through package redesign and opening technique. PLoS One. 2018;13(11):e0206892.	Quasi-experimental	136 individuals with practical experience in aseptic technique, United States	Four different pouch designs (a standard, one designed to curl in, another to curl out and one that incorporated a tab)	See intervention	Simulated contaminant (Glitterbug lotion)	Pouches designed with the material curled outward resulted in significantly fewer contacts with non-sterile surfaces than the other styles, including the inward, tab, and standard styles; this was true regardless of the used aseptic technique.	IIB
16	Applying Human Factors and Usability Engineering to Medical Devices. US Food & Drug Administration. February 3 , 2016. Accessed August 13, 2024. https://www.fda.gov/media/80481/download	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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17	Guideline for medical device and product evaluation. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:755–764.	Guideline	n/a	n/a	n/a	n/a	Provides guidance to perioperative team members for developing and implementing a process for evaluating FDA–cleared medical devices and products for use in the perioperative setting.	IVA
18	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
19	Bradley DF, Romito K, Dockery J et al. Reducing setup and turnover times in the OR with an innovative sterilization container: implications for the COVID-19 era military medicine. Mil Med. 2021;186(12 Suppl 2):35–39.	Organizational Experience	Military medical center, United States	n/a	n/a	n/a	When compared to the traditional method, the use of the Turbett Sterilization Pod resulted in improved turnover time, decreased room setup time, reduced environmental waste, and eliminated both the effect of damage to wrappers and the time previously spent wrapping surgical trays.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
20	Marchand KB, Taylor KB, Salem HS, Mont MA, Marchand RC. Surgical tray optimization and efficiency: the impact of a novel sealed sterile container and instrument tray technology. Surg Technol Int. 2020;37:349–355.	Quasi-experimental	Total knee arthroplasty, non-academic community-based hospital, United States	Novel sealed sterilization container, optimized instrument sets	Sterilization wrapped instrument sets, vendor trays	Time	The use of optimized trays and sealed sterilization containers reduced the turnover time by 57 minutes and the number of trays by a mean of three.	IIC
21	Seavey R. Using a systematic approach for adopting new technologies in sterile processing departments and operating rooms. Am J Infect Control. 2019;47S:A67–A71.	Expert Opinion	n/a	n/a	n/a	n/a	Organizations considering new technology should create a multidisciplinary risk assessment committee tasked with using a systematic approach to evaluate and make recommendations on new products or technologies.	VA
22	Final Guidance on Environmentally Preferable Purchasing. Environmental Protection Agency. 1999. Accessed August 13, 2024. https://www.epa.gov/sites/default/files/2015-09/documents/finaleppguidance.pdf	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	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	United Kingdom	n/a	n/a	Carbon footprint and financial costs	Carbon and financial savings can be made by preparing instruments as part of sets, integrating individually wrapped instruments into sets rather than streamlining them, efficient machine loading, and using low-carbon energy sources alongside recycling.	IIIB

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24	Wu S, Cerceo E. Sustainability initiatives in the operating room. Jt Comm J Qual Patient Saf. 2021;47(10):663–672.	Literature Review	n/a	n/a	n/a	n/a	Optimizing efficiency and decreasing waste generation can have a positive impact on the environment and can be accompanied by cost reduction.	VA
25	Balch JA, Krebs JR, Filiberto AC et al. Methods and evaluation metrics for reducing material waste in the operating room: a scoping review. Surgery. 2023;174(2):252–258.	Scoping Review	n/a	n/a	n/a	n/a	The most common intervention was instrument tray optimization. Common barriers to implementation included lack of stakeholder buy-in, knowledge gaps, data capture, additional staff time, need for hospital or federal policies, and funding.	IIIB
26	ANSI/AAMI ST41:2008/(R)2018: Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness. Association for the Advancement of Medical Instrumentation; 2018.	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
27	ANSI/AAMI ST65:2008/(R)2018: Processing of Reusable Surgical Textiles for Use in Health Care Facilities. 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
28	ANSI/AAMI ST58:2013/(R)2018: Chemical Sterilization and High-Level Disinfection in Health Care Facilities. 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

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
29	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
30	Guidelines for Design and Construction of Outpatient Facilities. 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

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
31	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
32	Jiang S, Yi L, Chen Y, Hu R. Optimizing sterilization packaging through root cause analysis: an exploration into sealing defects of paper-plastic pouches. Med Sci Monit. 2023;29:e940342.	Organizational Experience	Hospital, China	n/a	n/a	n/a	Implementing root cause analysis has been shown to effectively enhance the staff's perception of sealing quality and significantly reduce the incidence of sealing defects in paper-plastic pouches.	VA
33	Hospitals eTool. Central sterile supply: work-related musculoskeletal disorders. Occupational Safety and Health Administration. Accessed August 13, 2024. https://www.osha.gov/etools/hospitals/central-supply/work-related-musculoskeletal-disorders	Regulatory	n/a	n/a	n/a	n/a	OSHA guidance for preventing work-related musculoskeletal disorders in central sterile supply.	n/a

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34	Chen Y, Yi L, Hu J, Hu R. Factors associated with deficiencies in packaging of surgical instrument by staff at a single center in China. BMC Health Serv Res. 2022;22(1):660.	Nonexperimental	5000 surgical instrument packages, academic hospital, China	n/a	n/a	Defects in packaging	Various factors are associated with defects in surgical instrument packaging. Recommendations for reducing incidences of defects include improved scheduling of packaging workload, greater provision of training in packaging skills, and standardization of packaging procedure.	IIIB
35	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 hospital, United States	n/a	n/a	n/a	The 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
36	Price M, Bates A, Clagett M. Improving efficiency and standardization in a robotics program: a quality improvement project. AORN J. 2018;108(6):652–660.	Organizational Experience	Hospital, United States	n/a	n/a	n/a	By developing a team training program, improving operational efficiencies, and improving standardization, the robotics program achieved a 10-minute turn around time reduction and a 54% reduction in sterilized robotic instrument inventory.	VA

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37	Whelan J. Current issues in reprocessing of medical and surgical instruments. Am J Infect Control. 2023;51(10):1185–1188.	Expert Opinion	n/a	n/a	n/a	n/a	By the very nature of reusability, processing for reusable medical devices has been and continues to be risk prone. The identification of weak points and an openness to change are necessary to allow for a proactive culture of safety.	VA
38	Anazor F, Sibanda V, Altaf K, Downer L, Relwani J. The impact of sterile instrument set wrapping defects on trauma and orthopaedic surgery theatre lists. Cureus. 2022;14(10):e29861.	Organizational Experience	3 hospital sites, United Kingdom	n/a	n/a	n/a	Our study identified defects in the sterile instrument wrappings affecting both the inner with or without involving the outer wrapping layer and resulting in cancellation of elective and trauma orthopaedic cases with resultant clinical and financial implications.	VA
39	Ratwani RM, Adams KT, Kim TC et al. Assessing equipment, supplies, and devices for patient safety issues. Patient Safety. 2023;5(1):15–25.	Nonexperimental	450 patient safety event reports submitted to the Pennsylvania Patient Safety Reporting System	n/a	n/a	Medical equipment, supplies, and device events and reasons	Medical equipment, supplies, and device event-related patient safety issues, especially malfunctions, impact patient care despite current policies and practices to address these issues.	IIIB
40	Yi L, Chen Y, Hu R, Hu J, Pan W. Application of healthcare failure mode and effect analysis in controlling surgical instrument packaging defects. Sci Rep. 2022;12(1):19708.	Organizational Experience	Academic hospital, China	n/a	n/a	n/a	Using the medical failure mode and effect analysis method to control the defects in surgical instrument packaging can effectively reduce the packaging defect rate, ensuring patient safety.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
41	Guideline for prevention of unintentionally retained surgical items. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:797–860.	Guideline	n/a	n/a	n/a	n/a	Provides guidance to perioperative team members for preventing unintentionally retained surgical items.	IVA
42	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 Halsted 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
43	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	General practice in the United States is to sterilize ratcheted instruments in the open position.	VA

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44	Guideline for safe patient handling and movement. In: Guidelines for Perioperative Practice. AORN, Inc; 2024:861–892.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for developing an effective safe patient handling and movement (SPHM) program to reduce the incidence and minimize the severity of injuries to patients and health care workers related to performance of high-risk tasks.	IVA
45	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)	Cytotoxicity 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
46	Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care. Version 2.3. Centers for Disease Control and Prevention. September 2016. Accessed August 13, 2024. https://www.cdc.gov/infection-control/media/pdfs/Outpatient-Guide-508.pdf	Expert Opinion	n/a	n/a	n/a	n/a	Summary of infection prevention recommendations for outpatient settings based on CDC guidelines.	VA
47	ANSI/AAMI/ISO 11140-1:2014 Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements. 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

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48	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
49	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	912 instrument wrap identification of holes and tears by 48 staff on 20 instrument wrappers (one wrap subsequently found to have a tear that was not part of the study and was excluded)	n/a	n/a	Correct identification of a hole or tear in an instrument wrapper (Pass or Fail)	Trained OR personnel using standard processes for identification only correctly determined if an instrument wrapper was intact or had a hole or tear 56.1% of the time.	IIIB
50	Rashidifard CH, Mayassi HA, Bush CM et al. Looking for holes in sterile wrapping: how accurate are we? Clin Orthop Relat Res. 2018;476(5):1076–1080.	Nonexperimental	Thirty participants (OR RNs=13, STs = 10, Orthopedic Surgery Residents =7) & 46 instrument wrappers (36 with holes of various sizes, 10 controls)	n/a	n/a	Detection of holes of various sizes in instrument wrappers	Holes ≤ 2 mm were not reliably detected even with differences in participant experience levels or lighting source used (to enable detection). There was no correlation between detection accuracy and inspection time. Use of ambient light versus use of an overhead surgical light did not affect detection rates.	IIIB

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51	Kelly SR, Huish EG Jr, Holmboe MC, Lara DL, Trzeciak MA, Cash R. Detection of surgical wrap defects in the operating room setting. Orthopedics. 2021;44(6):e735–e738.	Nonexperimental	40 sterilization wraps 10 in each group with holes 1.2 mm, 3.7 mm, and 6.8 mm and no defects evaluated by 20 OR personnel	n/a	n/a	Detection of holes of various sizes in instrument wrappers	The smaller the hole the more likely that the hole will be missed. Large holes were only detected correctly 80% of the time. The best detections rates among staff was 77.5%.	IIIC
52	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
53	Law STH, Lee CK, Yeung WC et al. Performance test for sealing capability of rigid containers in central sterile supply departments in Tuen Mun Hospital and Pok Oi Hospital in Hong Kong. Zentralsterilisation (Wiesb). 2019;27(5):316–324.	Nonexperimental	1088 rigid containers, Hospital, China	n/a	n/a	Smoke Test, Paper Test, Water Leakage Test	The smoke test can serve as a supplement to validate the sealing capability of container as it can simulate the airborne transmission and the result is not affected by the external force and gravity.	IIIB

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54	State Operations Manual Appendix A: Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Rev. 220; 04-19-24. Centers for Medicare & Medicaid Services. Accessed August 13, 2024. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_a_hospitals.pdf	Regulatory	n/a	n/a	n/a	n/a	CMS condition of participation for hospitals.	n/a
55	State Operations Manual Appendix L – Guidance for Surveyors: Ambulatory Surgical Centers. Rev. 215, 07-21-23. Centers for Medicare and Medicaid Services. Accessed August 12, 2024. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_l_ambulatory.pdf	Regulatory	n/a	n/a	n/a	n/a	CMS conditions for coverage for ASCs.	n/a
56	Hoefel HHK, Pozzer C, Acunã A et al. Bundles for the central sterile supply department. Am J Infect Control. 2019;47(11):1352–1357.	Nonexperimental	11 professionals with at least 4 years of experience in sterilization, Brazil	n/a	n/a	Likert scale, agreement	Agreement among varying professionals was achieved, and bundles were successfully developed to evaluate the processing of goods in central sterile supply department.	IIIB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
57	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
58	Benze C, Spruce L, Groah L. Perioperative Nursing: Scope and Standards of Practice. AORN, Inc. 2021. Accessed August 13, 2024. https://www.aorn.org/docs/default-source/guidelines-resources/periop-nursing-scope-standards-of-practice.pdf?sfvrsn=c532cdee_1	Consensus	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
59	Dekonenko C, Oyetunji TA, Rentea RM. Surgical tray reduction for cost saving in pediatric surgical cases: a qualitative systematic review. J Pediatr Surg. 2020;55(11):2435–2441.	Systematic Review	n/a	n/a	n/a	n/a	Standardization of operating room doctor preference cards and surgical instrument trays in pediatric surgical cases result in lower operative supply costs without impacting OR time or safety.	IIIA

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60	Adamczyk AP, Kim PR, Horton I, Gofton W, Beaule PE, Grammatopoulos G. The SLIM Study: economic, energy, and waste savings through lowering of instrumentation mass in total hip arthroplasty. J Arthroplasty. 2022;37(8S):S796–S802.	RCT	Total hip arthroplasty, academic tertiary care center, Canada	Savings through Lowering of Instrumentation Mass (SLIM) setup	Standard setup	Operating room time, blood loss, perioperative adverse events and complications, cost/case, instrument weight (kg/case), total waste (kg/case), case setup time, and number of times and number of extra trays required	The SLIM setup is efficient and has been openly accepted by staff. Such setup can lead to 1,610 kg reduction in waste, 7,160 kWh, and $408,190 in savings per 1,000 THAs performed.	IA
61	Cichos KH, Hyde ZB, Mabry SE et al. Optimization of orthopedic surgical instrument trays: lean principles to reduce fixed operating room expenses. J Arthroplasty. 2019;34(12):2834–2840.	Quasi-experimental	Orthopedic trays, academic hospital, United States	Tray optimization	Before optimization	Instrument usage counts, cleaning times, room turnover times, tray weight, holes in tray wrapping, wet trays, time invested to optimize each tray, cost savings	In addition to substantial cost savings, tray optimization decreases tray weights and cleaning times without negatively impacting turnover times. Lean methodology improves efficiency in instrument tray usage, and reduces hospital cost while encouraging surgeon and staff participation through continuous process improvement.	IIB
62	Crosby L, Lortie E, Rotenberg B, Sowerby L. Surgical instrument optimization to reduce instrument processing and operating room setup time. Otolaryngol Head Neck Surg. 2020;162(2):215–219.	Quasi-experimental	86 trays used for tonsillectomy, sinus surgery, septoplasty, and septorhinoplasty; hospital, Canada	50 trays after optimization	36 trays before optimizations	Tray assembly time in central processing and instrument setup time in the OR	Measurable and significant time savings can be achieved by assessing instrument utilization rates and reducing tray redundancy, leading to lower performance variability and improved efficiency.	IIB

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63	Lonner JH, Goh GS, Sommer K et al. Minimizing surgical instrument burden increases operating room efficiency and reduces perioperative costs in total joint arthroplasty. J Arthroplasty. 2021;36(6):1857–1863.	Nonexperimental	35 elective primary total knee arthroplasty and total hip arthroplasty performed by 4 fellowship-trained surgeons, suburban community teaching hospital, United States	n/a	n/a	Type and number of instruments used as well as timing of different steps in the sterilization process were recorded by an independent observer	Lean methodology can be used to eliminate redundant or underutilized instruments in total joint arthroplasty, improving surgical efficiency and generating substantial cost savings.	IIIB
64	Toor J, Bhangu A, Wolfstadt J et al. Optimizing the surgical instrument tray to immediately increase efficiency and lower costs in the operating room. Can J Surg. 2022;65(2):E275–E281.	Nonexperimental	80 procedures using major orthopedic tray, large academic hospital, Canada	n/a	n/a	Instrument utilization by observation	The mathematical model yielded an additional 22% instrument reduction and $14230 in savings compared with clinician review alone.	IIIB
65	Dyas AR, Lovell KM, Balentine CJ et al. Reducing cost and improving operating room efficiency: examination of surgical instrument processing. J Surg Res. 2018;229:15–19.	Organizational Experience	Head and neck trays, hospital, United States	n/a	n/a	n/a	Optimizing surgical trays can reduce cost, physical strain, preparation time, decontamination time, and processing times, and streamlining trays is an effective strategy for hospitals to reduce costs and increase operating room efficiency.	VA
66	Fu TS, Msallak H, Namavarian A et al. Surgical tray optimization: a quality improvement initiative that reduces operating room costs. J Med Syst. 2021;45(8):78.	Organizational Experience	Otolaryngology procedures, community hospital, Canada	n/a	n/a	n/a	Surgical tray optimization is a simple, effective, and scalable strategy for reducing costs and improving OR efficiency without compromising patient safety.	VA

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67	Helmkamp JK, Le E, Hill I et al. Addressing surgical instrument oversupply: a focused literature review and case-study in orthopedic hand surgery. Hand (N Y). 2022;17(6):1250–1256.	Organizational Experience	Orthopedic hand surgery, ambulatory surgery center, United States	n/a	n/a	n/a	Instrument oversupply drives cost. Ethnography is a cost-effective method to track instrument utilization and determine optimal tray composition for small services but is not scalable to large health systems. The time and cost required to observe sufficient surgeries to enable supply reduction to motivate the need for more efficient methods to determine instrument utility.	VA
68	Herlihy E, Antao B, Fawaz A et al. Adapting lean methodology towards surgical tray rationalisation in inguinoscrotal day case surgery in the republic of Ireland. J Pediatr Urol. 2023;19(4):433.e1–433.e8.	Organizational Experience	Inguinoscrotal procedures, Ireland	n/a	n/a	n/a	The reduction in variation of this single surgical tray could lead to both operational as well as economic financial and ergonomic improvements for the healthcare system. The reduction in time taken to count and sterilize instruments can lead to potential manpower savings.	VA
69	Holland H, Kong A, Buchanan E, Patten C. Breast surgery cost savings through surgical tray instrument reduction. J Surg Res. 2022;280:495–500.	Organizational Experience	Breast procedures, hospital, United States	n/a	n/a	n/a	Optimizing surgical trays by removing unused instruments yields significant cost savings and contributes to improved efficiency in the sterile processing department.	VA

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70	Kirn PT, Angermeier E, Kokko KP. Reducing cost by using a smaller instrument tray in hand surgery. Curr Orthop Pract. 2018;29(6):565–568.	Organizational Experience	Hand surgery, academic medical center, United States	n/a	n/a	n/a	Processing fewer instruments in selected hand procedures is expected to result in significant cost savings and improvement in operating room workflow and satisfaction.	VA
71	Knowles M, Gay SS, Konchan SK et al. Data analysis of vascular surgery instrument trays yielded large cost and efficiency savings. J Vasc Surg. 2021;73(6):2144–2153.	Organizational Experience	Vascular surgery, academic medical center, United States	n/a	n/a	n/a	A comprehensive data analytics solution provided the ability to make informed decisions in tray management that otherwise could not be reliably performed.	VA
72	Ribes-Iborra J, Segarra B, Cortés-Tronch V et al. Improving perioperative management of surgical sets for trauma surgeries: the 4S approach. BMC Health Serv Res. 2022;22(1):1298.	Organizational Experience	ORIF procedures, academic medical center, Spain	n/a	n/a	n/a	This quality improvement study demonstrates the substantial time and cost savings, positive environmental impact and staff satisfaction that could be achieved by streamlining surgical set management through the 4S program.	VA
73	Schwartz JL, Kirkpatrick L, Hillebrecht KE et al. Cutting instruments to cut costs: a simple initiative with breast surgical operating room trays that resulted in substantial savings. Ann Surg Oncol. 2021;28(10):5553–5557.	Organizational Experience	Breast procedures, academic medical center, United States	n/a	n/a	n/a	Simply downsizing OR breast trays resulted in decreased combined personnel costs and unit supply costs per procedure, leading to a substantial cost savings for the healthcare system.	VA

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74	Yoon S, Zygourakis CC, Seaman J et al. Implementation and impact of a hospital-wide instrument set review: early experiences at a multisite tertiary care academic institution. Am J Med Qual. 2019;34(1):67–73.	Organizational Experience	Otolaryngology-Head and Neck Surgery procedures, 3 hospitals, academic medical center, United States	n/a	n/a	n/a	Through effective leadership, multidisciplinary participation of all key stakeholders, and a systematic approach, this study demonstrates that a hospital-wide quality improvement intervention for instrument set optimization can be successfully performed in a large, multisite tertiary care academic hospital.	VA
75	Yalamanchi P, Miller JE, Prout S et al. Association of operating room costs with head and neck surgical instrumentation optimization: a surgeon-led quality improvement initiative. JAMA Otolaryngol Head Neck Surg. 2022;148(5):402–407.	Organizational Experience	Head and neck surgery, large tertiary academic care center, United States	n/a	n/a	n/a	In this quality improvement study, surgeon-led elimination of redundant or rarely used instruments from surgical instrument trays was associated with reduced operating room direct costs while maintaining stakeholder satisfaction.	VA
76	Mitchell AR, Saleh JR. Water – an evaporating resource. Oper Tech Orthop. 2022;32(4):101000.	Literature Review	n/a	n/a	n/a	n/a	Eliminating rarely used surgical instruments from trays can save water and decrease costs to the hospital.	VC
77	Olivere LA, Hill IT, Thomas SM, Codd PJ, Rosenberger LH. Radiofrequency identification track for tray optimization: an instrument utilization pilot study in surgical oncology. J Surg Res. 2021;264:490–498.	Quasi-experimental	Oncology surgery, academic medical center, United States	RFID tags	Ethnography	Instrument use	Intraoperative RFID instrument tracking is a feasible, data-driven method for surgical tray reduction. Overall, RFID tracking represents a scalable, systematic, and efficient method of optimizing instrument supply across procedures.	IIC

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78	Wallis CB, Berend KR, Doucette DL, Lombardi AV Jr. Operating room efficiencies during total joint arthroplasty: be all they can be. Semin Arthroplasty. 2018;29(3):129–133.	Organizational Experience	Total joint arthroplasty, United States	n/a	n/a	n/a	Multiple protocols help improve operative day efficiencies including: time stamping, updating preference cards, streamlining instrument trays, proper staff education, and utilization of "swing" rooms. Efficiency has been shown to improve patient outcomes and contribute to cost savings. Real change is inspired by surgeon leadership and adopting an overall culture of efficiency.	VA
79	Rose ED, Modlin DM, Ciampa ML, Mangieri CW, Faler BJ, Bandera BC. Evaluation of operative waste in a military medical center: analysis of operating room cost and waste during surgical cases. Am Surg. 2019;85(7):717–720.	Organizational Experience	General surgery, military hospital, United States	n/a	n/a	n/a	On average for less complex cases such as open inguinal hernia repairs, $1.44 was potentially wasted per case, whereas for more complex cases up to $379 was wasted per case. Reasons contributing to wasted included outdated preference cards, lack of instrument knowledge, and distractions.	VB

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80	Mace Davis C, Spear JM. Instrument set decontamination workflows designed for success in sterile processing. AORN J. 2021;114(2):149–157.	Organizational Experience	4 hospital-based sterile processing departments, United States	n/a	n/a	n/a	Instrument count sheets were not accurate, including that instruments needed in the set were not listed on the count sheet. These inaccuracies were a source of communication problems between OR and sterile processing personnel. The count sheets were updated in a standardized format, which streamlined workflows in sterile processing.	VA