REF#	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	SCORE
1	*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff.* US Food & Drug Administration (FDA); 2015. Accessed August 12, 2025. https://www.fda.gov/media/80265/download	Regulatory	n/a	n/a	n/a	n/a	FDA guidance to manufacturers which provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices; the content and review of premarket notification submissions [510(k)], premarket (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. 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 the device can be used safely and for the purpose for which it is intended.	n/a
2	Rutala WA, Weber DJ; Healthcare Infection Control Practices Advisory Committee (HICPAC). *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008* . Centers for Disease Control and Prevention. Updated June 2024. Accessed August 12, 2025. https://www.cdc.gov/infection-control/media/pdfs/Guideline-Disinfection-H.pdf	Guideline	n/a	n/a	n/a	n/a	This guideline presents evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patientcare medical devices and for cleaning and disinfecting the healthcare environment. Makes evidence-based recommendations for disinfection and sterilization of surgical instruments and other medical devices. The guideline stresses the importance of effective cleaning as a first step in processing medical devices.	IVA
3	Berrios-Torres SI, Umscheid CA, Bratzler DW et al.; Healthcare Infection Control Practices Advisory Committee. 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	Use of personal protective equipment (PPE)	Systematic review including 170 studies with conclusions reached regarding preoperative bathing, antimicrobial prophylaxis, preoperative skin antisepsis, glycemic control, normothermia, blood transfusion, oxygen supplementation, instrument processing, and quality improvement programs.	IVA
4	*ANSI/AAMI ST79/(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 (AAMI); 2017.	Consensus	n/a	n/a	n/a	n/a	Consensus standard that covers steam sterilization in health care facilities, and handling of surgical instruments and other medical devices leading up to sterilization. Discusses environmental conditions for these.	IVC
5	Reprocessing of reusable medical devices. US Food and Drug Administration. January 10 , 2023. Accessed August 12, 2025. https://www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-reusable-medical-devices	Regulatory	n/a	n/a	n/a	n/a	Website with information about reprocessing of reusable medical devices, the challenges of reprocessing and ways the FDA is helping address problems with today's reprocessed devices, notably duodenoscopes, while facilitating improvements in innovative design of the next generation of these devices. Includes information about reporting adverse events to the FDA	n/a
6	Guideline for sterilization. In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:1049–1082	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for sterilization practices in the health care organization	IVA
7	Guideline for sterilization packaging systems. In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:603–622	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for sterilization packaging systems used in the health care organization	IVA

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8	Guideline for manual high-level disinfection. In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:315–338	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for manual high-level disinfection in the perioperative area	IVA
9	Guideline for processing flexible endoscopes. In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:227–276.	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for processing flexible endoscopes	IVA
10	21 CFR §860 . Medical device classification procedures. Code of Federal Regulations. Accessed August 12, 2025. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-860	Regulatory	n/a	n/a	n/a	n/a	US Code of Federal Regulations which implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use and prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices.	n/a
11	21 CFR 814: Premarket Approval of Medical21 CFR §814 . Premarket approval of medical devices. Code of Federal Regulations. Accessed August 12, 2025. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-814 Devices 2024	Regulatory	n/a	n/a	n/a	n/a	US Code of Federal Regulations which establishes an efficient and thorough device review process to facilitate the approval of PMA's for devices that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval; and to ensure the disapproval of PMA's for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval.	n/a
12	21 CFR §807.81 . When a premarket notification submission is required. Code of Federal Regulations. Accessed August 12, 2025. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-E/section-807.81	Regulatory	n/a	n/a	n/a	n/a	US Code of Federal Regulations which describes the process for introducing a medical device to the market that is exempt from Premarket Approval of Medical devices.	n/a
13	*AAMI TIR12:2020/(R)2023; Designing, Testing, and Labeling Medical Devices Intended for Processing by Health Care Facilities: A Guide for Device Manufacturers.* Association for the Advancement of Medical Instrumentation; 2020.	Consensus	n/a	n/a	n/a	n/a	Covers design considerations that medical device manufacturers should take into account to help ensure that their products can be safely and effectively reprocessed and 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. In addition, labeling recommendations and information on applicable regulations.	IVC
14	*ANSI/AAMI/ISO 17664-1:2022; Processing of Health Care Products – Information to be Provided by the Medical Device Manufacturer for the Processing of Medical Devices – Part 1: Critical and Semi-Critical Medical Devices* . Association for the Advancement of Medical Instrumentation; 2022	Consensus	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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15	Shenoy ES, Weber DJ, McMullen K et al. Multisociety guidance for sterilization and high-level disinfection. *Infect Control Hosp Epidemiol* . 2025;46(6):561–583. doi: 10.1017/ice.2025.41	Consensus	n/a	n/a	n/a	n/a	This guidance document focuses on sterilization and HLD for healthcare facilities, including all locations where healthcare is delivered.	IVB
16	*ASTM E2314-03: Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)* . ASTM International; 2010	Consensus	n/a	n/a	n/a	n/a	International consensus standards that describes microbiologic test methods for medical device cleaning validation study.	IVC
17	Guideline for medical device and product evaluation In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:797–806	Guideline	n/a	n/a	n/a	n/a	Evidence-based practice recommendations for perioperative medical device and product evaluation	IVA
18	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
19	Crawford M. How clean is clean? Chemistry can damage medical equipment in the quest to meet stringent guidelines. *Biomed Instrum Technol* . 2014;48(4):260–263	Expert Opinion	n/a	n/a	n/a	n/a	Clinical engineering departments and healthcare technology managers must be involved in developing thorough systems for evaluating new detergents and cleaners used in instrument care and cleaning; time allocation for thorough testing all cleaners on as many devices as possible is needed.	VB
20	Final guidance on environmentally preferable purchasing for executive agencies. *Fed Regist* . 1999;64(161):45810.	Regulatory	n/a	n/a	n/a	n/a	EPA guidance on environmentally preferable purchasing in the US	n/a
21	Stiefel P, Mauerhofer S, Schneider J, Maniura-Weber K, Rosenberg U, Ren Q. Enzymes enhance biofilm removal efficiency of cleaners. *Antimicrob Agents Chemother* . 2016;60(6):3647–3652	Quasi-experimental	biofilm removal assay using 96-well plates	treatment using enzymes	positive and negative controls	presence of biofilm	The addition of enzymes to the base formulation had a clear beneficial effect on the efficiency of biofilm removal. The S. aureus biofilm was removed efficiently if an active protease was present, whereas for P. aeruginosa, single enzymes added to the formulation were not sufficient. An optimized enzyme mixture including protease, polysaccharides, and other enzymes in a selected base formulation was required to achieve efficient removal o fP. aeruginosa. Therefore, many commercial products displayed good performance against S. aureus and blood contamination but had problems with the removal of P. aeruginosa biofilms. Non-enzymatic cleaners were not effective in either blood cleaning or biofilm removal but rather worked as a disinfectant, killing the bacteria.	IIA
22	Juturu V, Wu JC. Microbial cellulases: engineering, production and applications. *Renew Sustain Energy Rev.* 2014;33:188–203	Expert Opinion	n/a	n/a	n/a	n/a	Description of different microbial cellulases in practice and relevant enzymatic solutions	VA
23	Kremer TA, Olsen D, Summers C et al. Assessing detergent residuals for reusable device cleaning validations. *Biomed Instrum Technol* . 2021;55(4):165–170	Nonexperimental	Laboratory, United States	n/a	Various detergents, both enzymatic and nonenzymatic	Cytotoxicity	Rinsing of detergent is critical for patient safety. Very few detergent manufacturers provide enough detail on toxicity profiles and rinsing instruction. This work can help processing personnel assess residual detergent risks, including interference with subsequent processing steps and cytotoxicity.	IIIB

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24	*ANSI/AAMI ST98:2022; Cleaning Validation of Health Care Products—Requirements for Development and Validation of a Cleaning Process for Medical Devices* . Association for the Advancement of Medical Instrumentation; 2022	Consensus	n/a	n/a	n/a	n/a	Consensus recommendations for validation of cleaning processes for medical devices.	IVC
25	Medical washers and medical washer-disinfectors – Class II special controls guidance document for the medical device industry and FDA review staff. US Food and Drug Administration. February 7 , 2002. Accessed August 12, 2025. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/medical-washers-and-medical-washer-disinfectors-class-ii-special-controls-guidance-document-medical	Regulatory	n/a	n/a	n/a	n/a	A medical washer or washer-disinfector is a medical device intended to process medical devices. The FDA regulates the introduction of medical devices in interstate commerce. A medical washer disinfector intended to clean and provide high level disinfection of medical devices must have a FDA cleared premarket notification [510(k)] submission before it can be sold.	n/a
26	*AAMI TIR55:2014/(R)2017. Human Factors Engineering for Processing Medical Devices.* Association for the Advancement of Medical Instrumentation; 2017	Consensus	n/a	n/a	n/a	n/a	Provides guidance on the application of human factors engineering principles to instructions provided by manufacturers for cleaning medical devices.	IVC
27	Moss R, Prescott DM, Spear JM. Instrument manufacturing: implications for perioperative teams. *AORN J* . 2020;112(1):15–29	Expert Opinion	n/a	n/a	n/a	n/a	Knowledge about surgical instrument manufacturing should help perioperative teams provide safer care for their patients.	VB
28	Rutala WA, Boyce JM, Weber DJ. Disinfection, sterilization and antisepsis: an overview. *Am J Infect Control* . 2023;51(11 suppl):A3–A12	Literature Review	n/a	n/a	n/a	n/a	Strict adherence to current disinfection and sterilization guidelines is essential to prevent patient infections and exposures to infectious agents.	VA
29	*ANSI/AAMI ST58:2024. Chemical Sterilization and High-Level Disinfection in Health Care Facilities.* Association for the Advancement of Medical Instrumentation; 2024	Consensus	n/a	n/a	n/a	n/a	Consensus standard on the selection and use of liquid chemical sterilants (LCSs)/high-level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the 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 high-level disinfection; quality control methods; and quality process improvement. Definitions of terms and informative annexes are also provided.	IVC
30	*ST91:2021; Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities.* Association for the Advancement of Medical Instrumentation (AAMI); 2021	Consensus	n/a	n/a	n/a	n/a	Consensus recommendations for processing flexible and semi-rigid endoscopes in health care.	IVC

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31	Class 2 device recall BIOMET Orthopedics. US Food and Drug Administration. April 3 , 2020. Accessed September 22, 2025. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=180539	Regulatory	n/a	n/a	n/a	n/a	Potentially insufficient cleaning process or potential inadequate process monitoring for cleaning parameters.	n/a
32	Costa DM, Lopes LKO, Vickery K et al. Reprocessing safety issues associated with complex-design orthopaedic loaned surgical instruments and implants. *Injury*. 2018;49(11):2005–2012	Quasi-experimental	Flexible medullary reamers, depth gauges, and screws used for femur IM nailing in clinical use for >1 year.	cleaning and steam sterilization	comparison within group	Following cleaning and sterilization, biofilm and soil, including fragments appearing to be bone, were detected by scanning electron microscopy on RSIs/screws. A sterilized FMR revealed visible soil on the inner layer. Endotoxin tests were negative.	The contaminated condition of loaned-complex-designed RSIs/screws upon arrival at the hospital and after reprocessing points to the insufficiency of manual reprocessing and management practices related to this instruments/implants. A multidisciplinary approach involving expert in design/manufacture, regulating, managing, reprocessing and surgeons is suggested to improve RSIs manufacture that enables complete decontamination and maintain the surgical patient safety.	IIB
33	Tipple AFV, Costa DM, Lopes LKO et al. Reprocessing of loaned surgical instruments/implants in Australia and Brazil: a survey of those at the coalface. *Infect Dis Health* . 2022;27(1):23–30	Nonexperimental	65 questionnaires from Australia, 168 from Brazil	n/a	Comparison between practices in Australia (high-income) and Brazil (middle-income)	Quality indicators regarding structure and work process for reprocessing	Quality indicators regarding structure and work process for the management and reprocessing of loaned surgical implants and nonsterile implants was of a higher standard in Australia than in Brazil. However, failures were detected in both countries, for instance delivery delays and improper point-of-use pre-cleaning practice. Initial and ongoing education and training should be provided and should embrace the themes of technical proficiency, effective communication and teamwork, and should include all personnel involved in this process, even loaner company staff.	IIIB
34	Guideline for design and maintenance of the surgical suite. In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:79–142	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for providing for optimal surgical suite design and maintenance	IVA
35	*Guidelines for Design and Construction of Hospitals* . The Facility Guidelines Institute; 2022	Guideline	n/a	n/a	n/a	n/a	The document provides 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

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36	*Guidelines for Design and Construction of Outpatient Facilities.* The Facility Guidelines Institute; 2022	Guideline	n/a	n/a	n/a	n/a	The document provides minimum design standards for a variety of outpatient facility types, including general and specialty medical services facilities, outpatient imaging facilities, birth centers, urgent care facilities, infusion centers, outpatient surgery facilities, freestanding emergency facilities, endoscopy facilities, renal dialysis centers, outpatient psychiatric facilities, outpatient rehabilitation facilities, mobile/transportable medical units, and dental facilities. Guidance is provided for applying the Guidelines to outpatient facilities of numerous types, both freestanding and part of existing facilities, including those not specifically addressed in the document.	IVC
37	Guideline for a safe environment of care. In: *Guidelines for Perioperative Practice.* AORN Inc; 2025:165–196	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for providing a safe environment of care for perioperative patients and personnel	IVA
38	Ofstead CL, Hopkins KM, Daniels FE, Smart AG, Wetzler HP. Splash generation and droplet dispersal in a well-designed, centralized high-level disinfection unit. *Am J Infect Control* . 2022;50(11):1200–1207	Organizational Experience	Large urban hospital, United States	n/a	n/a	Detection of droplets on chemical indicator paper, distance of droplets, PPE exposure to droplets	Manual cleaning of devices generated substantial splash, drenching technicians and the environment with droplets that traveled more than 7 feet.	VB
39	Ofstead CL, Hopkins KM, Smart AG, Brewer MK. Droplet dispersal in decontamination areas of instrument reprocessing suites. *Am J Infect Control.* 2022;50(2):126–132.	Organizational Experience	Large urban hospital, United States	n/a	n/a	Detection of droplets on chemical indicator paper, distance of droplets, PPE exposure to droplets	Droplets traveled at least 3 feet when filling a sink, brushing a ureteroscope, and using a power sprayer to rinse a basin. Some activities dispersed droplets up to 5 feet from the sink. Personal protective equipment was splashed during most activities and did not prevent skin exposure even when properly donned and doffed, especially at the glove-gown interface.	VB
40	29 CFR §1910.151 . Medical services and first aid. Code of Federal Regulations. Accessed August 13, 2025. https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-K/section-1910.151	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations (law) regarding medical services and first aid	n/a
41	29 CFR §1910.1030. Bloodborne pathogens. Accessed August 13, 2025. https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-Z/section-1910.1030	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations (law) regarding bloodborne pathogens	n/a
42	Alfa MJ, Olson N, Al-Fadhaly A. Cleaning efficacy of medical device washers in North American healthcare facilities. *J Hosp Infect* . 2010;74(2):168–177	Nonexperimental	Observation of residual protein, hemoglobin, carbohydrate, and endotoxin after cleaning of five instruments (swabs each 4, 4, 3,2,1 respectively)	n/a	n/a	residual hemoglobin and protein correlated to visual score for TOSI device	Supports the need to monitor the water quality used in instrument washers. In addition, there is an urgent need for establishment of standardized criteria for rapid cleaning indicators for instrument washers to ensure that they provide a clinically relevant method for monitoring washers used in healthcare facilities.	IIIA

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43	*ASTM D7225-13(2019)e1: Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors* . ASTM International; 2019	Consensus	n/a	n/a	n/a	n/a	This is a guidance document for performing tests that measure performance of washer-disinfectors sing standardized test soils; published by ASTM International.	IVC
44	Rutala WA, Gergen MF, Weber DJ. Efficacy of a washer-disinfector in eliminating healthcare-associated pathogens from surgical instruments. Infect *Control Hosp Epidemiol.* 2014;35(7):883–885	Quasi-experimental	4 instruments inoculated with test organisms	inoculation, air drying for one hour, and processing in a washer-disinfector	positive control by bioburden extraction from surgical instruments that were inoculated under same conditions as test instruments and not processed in washer-disinfector	mean log reduction of inoculum with test organisms	A washer-disinfector was effective in eliminating microorganisms (>7-log(10) reduction), including vegetative and spore-forming bacteria, from experimentally contaminated instruments. The washer-disinfector remained effective in eliminating microorganisms in the absence of enzymatic cleaners and detergents.	IIA
45	Evangelista SS, Guimaraes NR, Garcia NB, Santos SGD, Oliveira AC. Effectiveness of manual versus automated cleaning on *Staphylococcus epidermidis* biofilm removal from the surface of surgical instruments. *Am J Infect Control* . 2020;48(3):267–274	Nonexperimental	Surgical instruments (crile forceps) contaminated with Staphylococcus epidermidis, Brazil	Manual cleaning with enzymatic detergent and automated ultrasonic cleaning	Positive control (contaminated fragments without cleaning)	Microbial load (CFU/cm²) and biofilm presence (SEM analysis)	Automated cleaning was more effective than manual cleaning in reducing microbial load, but neither method completely removed biofilms.	IIC
46	Weber DJ, Rutala WA, Anderson DJ, Sickbert-Bennett EE. Biofilms on medical instruments and surfaces: do they interfere with instrument reprocessing and surface disinfection. *Am J Infect Contro* l. 2023;51(11 suppl):A114–A119	Literature Review	n/a	n/a	n/a	n/a	Despite the bioburden on used surgical instruments, decontamination is recommended for the following 2 reasons: (1) it protects the staff handling the instruments from acquiring infection in the event of a percutaneous injury; and (2) it reduces the microbial contamination on instruments as well as protein and salt before sterilization and thereby enhances the reliability of the sterilization process. Surgical instruments should be cleaned in a washer-disinfector prior to sterilization.	VA
47	Uetera Y, Kishii K, Yasuhara H et al. A 5 year longitudinal study of water quality for final rinsing in the single chamber washer-disinfector with a reverse osmosis plant. *PDA J Pharm Sci Technol* . 2013;67(4):399–411	Organizational Experience	Military treatment facility, United States	n/a	n/a	n/a	Adenosine triphosphate (ATP)–based technology was a viable and affordable solution for detecting bioburden and validating cleaning practices. The project design compared manually and mechanically cleaned cannulated instruments (59 of each) and identified 16 contaminated instruments, 14 of which had been manually cleaned. The contamination rate after mechanical cleaning was significantly lower (P = .0022) compared with manual cleaning.	VA

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48	Uetera Y, Kishii K, Yasuhara H et al. A 5 year longitudinal study of water quality for final rinsing in the single chamber washer-disinfector with a reverse osmosis plant. *PDA J Pharm Sci Techno* l. 2013;67(4):399–411	Case Report	n/a	n/a	n/a	n/a	Case report analyzing the construction and management of the reverse osmosis (RO) water system for final rinsing of surgical instruments in the washer-disinfector to find potential problems and promote preventive system management for RO water. The storage tank was significantly contaminated and had to be replaced with a new one equipped with a sampling port and water drainage system. Additional filters and an UV treatment lamp were installed. The whole system disinfection started 1.5 years later using a peracetic acid- based compound after confirming the material compatibility. When a new water engineer came onto the job, operator errors were found, and some deficiencies in the standard operating procedures (SOPs) were found, and on-the-job training was not enough. The water engineer failed to disinfect the sampling port and water drainage system. The RO membrane had been used for 4 years, even though the SOP standard specified changing it as every 3 years. Various bacteria were cultured from the RO water sampled from the equipment. Water systems should be designed based on the plans for profound system maintenance and SOP and on-the job training are essential to avoid any operator errors.	VA
49	*ANSI/AAMI ST108: Water for the Processing of Medical Devices.* Association for the Advancement of Medical Instrumentation; 2023	Consensus	n/a	n/a	n/a	n/a	This standard covers the selection and maintenance of effective water quality suitable for processing medical devices.	IVC
50	Central sterile supply: work-related musculoskeletal disorders. Occupational Safety and Health Administration. Accessed August 13, 2025. 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
51	Nino L, Marchak F, Claudio D. Physical and mental workload interactions in a sterile processing department. Int *J Ind Ergon.* 2020;76:102902	Nonexperimental	12 SPD employees (Phase 1-3), 18 volunteers (Phase 4), United States	n/a	Normal days vs. busy days, Load vs. Unload conditions	Ergonomic assessment using REBA, mental workload assessment using NASA-TLX	Increases in mental workload are associated with more risky body postures, increasing the risk of developing musculoskeletal disorders. These results serve to raise awareness and warn employees about the need to pause and analyze the way they perform their duties under high levels of workload.	IIIB

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52	Whapham CA, Walker JT. Too much ado about data: continuous remote monitoring of water temperatures, circulation and throughput can assist in the reduction of hospital-associated waterborne infections. *J Hosp Infect* . 2024;152:47–55	Literature Review	n/a	n/a	n/a	n/a	Widespread glove use, alcohol gel and wipes have increased water system stagnancy resulting in amplification of waterborne pathogens and transmission risk of legionella, pseudomonas, and non-tuberculous mycobacteria. Manual monitoring does not represent temperatures across large complex water systems. This review deems that multiple-point continuous remote sensor monitoring is effective at identifying redundant and low use outlets, hydraulic imbalance and inconsistent temperature delivery across in-premises water systems.	VA
53	Hsu MS, Wu MY, Huang YT, Liao CH. Efficacy of chlorine dioxide disinfection to non-fermentative Gram-negative bacilli and non-tuberculous mycobacteria in a hospital water system. *J Hosp Infect.* 2016;93(1):22–28	Organizational Experience	ClO2 treatment in a 1000-bed medical center with two towers and three ICUs.	n/a	n/a	n/a	Addition of a ClO2 disinfection unit to our hospital water system reduced the numbers of non-tuberculous mycobacteria and non-fermentative Gram-negative bacilli in the hot and cold water systems.	VB
54	*Developing a Water Management Program to Reduce Legionella Growth & Spread in Buildings: A Practical Guide to Implementing Industry Standards.* Centers for Disease Control and Prevention. June 24 , 2021. Accessed August 13, 2025. https://www.cdc.gov/control-legionella/media/pdfs/toolkit.pdf	Expert Opinion	n/a	n/a	n/a	Behaviors after accidents	CDC guidance and tool kit for creating a water management program required by CMS	VA
55		Regulatory	n/a	n/a	n/a	n/a	Requirements for health care facilities regarding water quality systems to prevent transmission of legionella	n/a
56	Perkins KM, Reddy SC, Fagan R, Arduino MJ, Perz JF. Investigation of healthcare infection risks from water-related organisms: summary of CDC consultations, 2014—2017. *Infect Control Hosp Epidemiol* . 2019;40(6):621–626	Organizational Experience	134 consultations with 1,380 patients	n/a	n/a	n/a	Review highlights the contribution of water-related organisms to healthcare outbreaks and transmission and helps illustrate the challenges surrounding their investigation and prevention.	VA
57	Marek A, Smith A, Peat M et al. Endoscopy supply water and final rinse testing: five years of experience. *J Hosp Infect* . 2014;88(4):207–212	Organizational Experience	Three endoscope reprocessing units, each comprising five endoscope washer-disinfectors (EWDs) supplied by two reverse osmosis (RO) water units, were subjected to weekly monitoring and control of final rinse water quality.	n/a	n/a	n/a	Quality control principles coupled with appropriate thermal and chemical disinfection of EWDs resulted in the achievement of microbiological standards for final rinse water. A coordinated team approach between the microbiology department, infection control department, endoscope unit managers and estates department is required to achieve this degree of success.	VA
58	Borella P, Bargellini A, Marchegiano P, Vecchi E, Marchesi I. Hospital-acquired Legionella infections: an update on the procedures for controlling environmental contamination. *Ann Ig* . 2016;28(2):98–108	Literature Review	n/a	n/a	n/a	n/a	The performance ranking for water quality control measures was highest for the filter, followed by boilers at high temperature, monochloramine and, at a lower level, chlorine dioxide; the effectiveness of hyperchlorination was limited, and thermal shock was even more ineffective.	VA

REF#	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	SCORE
59	Casini B, Buzzigoli A, Cristina ML et al. Long-term effects of hospital water network disinfection on Legionella and other waterborne bacteria in an Italian university hospital. *Infect Control Hosp Epidemiol* . 2014;35(3):293–299	Nonexperimental	One university hospital experience with a water safety plan to control Legionella over the course of 9 years.	n/a	n/a	Training on occupational risks	After 9 years, the integrated disinfection-filtration strategy implemented as part of the water safety plan significantly reduced positive sample sites by 55% and the mean count by 78% (P < .05); however, the high costs and the occurrence of a chlorine-tolerant clone belonging to Legionella pneumophila ST269 prompted us to test a new disinfectant. The shift to monochloramine eliminated planktonic Legionella and did not require additional endpoint filtration; however, nontuberculous mycobacteria were isolated more frequently as long as the monochloramine concentration was 2 mg/L; their cultivability was never regained by increasing the concentration up to 3 mg/L. Any disinfection method needs to be continually evaluated and adjusted in individual hospitals to maintain results over time, and only a locally-adapted evidence-based approach allows assessment of the efficacy and disadvantages of the control measures.	IIIA
60	D'Alessandro D, Fabiani M, Cerquetani F, Orsi GB. Trend of Legionella colonization in hospital water supply. Ann Ig. 2015;27(2):460–466	Quasi-experimental	97 samples collected from hospital water line from 2003 to 2010	different water treatment interventions including chlorides	building age, residual chlorine	presence of Legionella	Overall 28 samples (23.7%) were positive for Legionella spp, and five of them (17.9%) exceeded the threshold level >104 cfu/L. The number of positive samples varied along the years, showing a significant increasing trend (X2 for trend = 11.5; p104 cfu/L occurred in the C-building. No cases of nosocomial legionellosis were reported during the study period. Hospital water system showed a diffuse colonization by Legionella spp, although the degree of contamination reached the threshold level (>104 cfu/L) only in a small percentage of samples, showing a substantial effectiveness of the control measures applied.	IIB

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61	Marinelli L, Cottarelli A, Solimini AG, Del Cimmuto A, De Giusti M. Evaluation of timing of re-appearance of VBNC Legionella for risk assessment in hospital water distribution systems. *Ann Ig* . 2017;29(5):431–439	Nonexperimental	An outbreak and contributing factors in a single hospital using copper-silver ionization for prevention of Legionella growth in water.	n/a	n/a	Five definite and 17 probable healthcare-associated Legionella cases; 6 case patients died. Of 25 locations (mostly potable water) where environmental samples were obtained for Legionella-specific culture, all but 2 showed Legionella growth; 11 isolates were identical to 3 clinical isolates by sequence-based typing. Mean copper and silver concentrations were at or above the manufacturer's recommended target for Legionella control. Despite this, all samples where copper and silver concentrations were tested showed Legionella growth.	This outbreak was linked to the hospital's potable water system and highlights the importance of maintaining a high index of suspicion for healthcare-associated Legionnaire's Disease, even in the setting of a long-term disinfection program.	IIIB

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62	Marinelli L, Cottarelli A, Solimini AG, Del Cimmuto A, De Giusti M. Evaluation of timing of re-appearance of VBNC Legionella for risk assessment in hospital water distribution systems. *Ann Ig.* 2017;29(5):431–439	Nonexperimental	Presence of Legionella species, viable but non-culturable (VBNC), in hospital water networks and the time and load of Legionella appearance in samples found negative using the standard culture method.	n/a	n/a	42 samples was obtained from the tap water of five hospital buildings. The samples were tested for Legionella by the standard culture method and were monitored for up to 12 months for the appearance of VBNC Legionella. RESULTS: All the 42 samples were negative at the time of collection. Seven of the 42 samples (17.0%) became positive for Legionella at different times of monitoring. The time to the appearance of VBNC Legionella was extremely variable, from 15 days to 9 months from sampling. The most frequent Legionella species observed were Legionella spp and L. anisa and only in one sample L. pneumophila	Confirms the presence of VBNC Legionella in samples resulting negative using the standard culture method and highlights the different time to its appearance that can occur several months after sampling. The results are important for risk assessment and risk management of engineered water systems.	IIIB
63	Donohue MJ, Vesper S, Mistry J, Donohue JM. Impact of chlorine and chloramine on the detection and quantification of Legionella pneumophila an. Mycobacterium species. *Appl Environ Microbiol.* 2019;85(24):e01942–19	Quasi-experimental	358 water samples from 46 states in the United States	Chlorine disinfection	Chloramine disinfection	Detection and quantification of Legionella pneumophila and Mycobacterium species using qPCR	Chlorine was more effective for controlling Mycobacterium species, while chloramine was more effective for controlling Legionella pneumophila. No single water characteristic achieved microbial control for all pathogens.	IIB

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64	Moore G, Stevenson D, Thompson KA et al. Biofilm formation in an experimental water distribution system: the contamination of non-touch sensor taps and the implication for healthcare. *Biofouling.* 2015;31(9-10):677–687	Quasi-experimental	27 tap assemblies	P. aeruginosa was injected into 27 individual tap 'assemblies'. Taps were subsequently flushed twice daily and contamination levels monitored over two years. Tap assemblies were systematically dismantled and assessed microbiologically and the effect of removing potentially contaminated components was determined. P. aeruginosa was repeatedly recovered from the tap water at levels above the augmented care alert level.	with and without solenoid valves in the individual tap assemblies	Presence of detectible levels of p. aeruginosa	P. aeruginosa was recovered from all dismantled solenoid valves with colonization of the ethylene propylene diene monomer (EPDM) diaphragm . Removing the solenoid valves reduced P. aeruginosa counts in the water to below detectable levels. This effect was immediate and sustained, implicating the solenoid diaphragm as the primary contamination source for p. aeruginosa.	IIA
65	Yui S, Karia K, Ali S. Evaluation of novel disinfection methods for the remediation of heavily contaminated thermostatic mixing valves and water systems with Pseudomonas aeruginosa biofilm: considerations for new and existing healthcare water systems. *J Hosp Infect* . 2024;151:195–200	Quasi-experimental	Simulated tap system (polyethylene and copper piping) with Pseudomonas aeruginosa biofilm, Laboratory, United Kingdom	4 disinfection methods: (1) mechanical flushing, (2) peracetic acid disinfection, (3) in-tap thermal disinfection, (4) in-line thermal disinfection	Comparison of disinfection methods	Levels of Pseudomonas aeruginosa in water samples	In-line thermal flushing was the most effective method to remove P. aeruginosa biofilm. Results vary with the strain of bacteria and plumbing composition. Combination of methods may be necessary to remove established biofilm.	IIB
66	Bhalchandra R, Chandy M, Ramanan VR et al. Role of water quality assessments in hospital infection control: experience from a new oncology center in eastern India. *Indian J Pathol Microbiol* . 2014;57(3):435–438	Organizational Experience	observation of water quality parameters (presence of microorganisms, total dissolved solids, free residual chlorine) in a new oncology and bone marrow transplantation center in Eastern India	n/a	n/a	n/a	4 cardinal events were identified in the center during the observation period including Pseudomonas aeruginosa in hospital RO water supply, high TDS in the central sterile processing department and surgical hand antisepsis sinks, high colony count in the supply of drinking water, and a damaged strainer of sand filter in the RO plant detected with the TDS meter.	VA

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67	*Decontamination and Reprocessing of Medical Devices for Health-Care Facilities.* World Health Organization and Pan American Health Organization; 2016. Accessed August 13, 2025. https://www.who.int/publications/i/item/9789241549851	Guideline	n/a	n/a	n/a	n/a	World Health Organization guideline for decontamination and processing of medical devices	IVB
68	Guideline for transmission-based precautions. In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:1179–1206	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for perioperative transmission-based precautions	IVA
69	*Standards of Practice for the Decontamination of Surgical Instruments.* Association of Surgical Technologists; 2009.	Consensus	n/a	n/a	n/a	n/a	AST guideline for the role of the surgical technologist during decontamination of surgical instruments.	IVC
70	Resendiz M, Horseman TS, Hover AJ, Bradley DF, Lustik MB, West GF. Assessment of surgical instrument bioburden after steam sterilization: a pilot study. *Am J Infect Contro* l. 2020;48(2):219–221	Organizational Experience	69 endoscopes, 4 hospitals, United States	n/a	n/a	Microbial cultures, visual inspection, interviewing hospital personnel	Microbial cultures were positive for ≥50% of fully reprocessed endoscopes. Researchers observed cloudy, shimmery fluid resembling simethicone inside channels and under a duodenoscope elevator mechanism. Crystallized white fragments were observed protruding from a gastroscope water jet outlet. Oily, sticky residue was found on endoscopes, and a mass was found inside an endoscopic ultrasound endoscope. Hospital personnel reported the use of simethicone, cooking oil and silicone sprays, and tissue glue during endoscopy.	VA
71	Resendiz, Marisol, Horseman, Timothy S., Hover, Andrew J., Bradley, David F., Lustik, Michael B. and West, Gordon F. Assessment of surgical instrument bioburden after steam sterilization: A pilot study 2020	Quasi-experimental	60 sets of surgical instruments inoculated with test organisms (P aeruginosa, S aureus, B subtilis), United States	1 instrument per set contaminated with blood	Comparison between wrapped and unwrapped sets undergoing sterilization	Bacterial growth on instruments	The results of this pilot study suggest inadequate efficacy of steam sterilization on air dried debris and provide evidence that contaminated instruments pose a risk to clean instruments in the set. Although wrapping of instruments has become standard of practice, this study showed a tendency for increased survivability of target bacteria in wrapped versus unwrapped sets (although not statistically significant).	IIA
72	Rutala WA, Gergen MF, Weber DJ. Does blood on "dirty" instruments interfere with the effectiveness of sterilization technologies? *Infect Control Hosp Epidemiol* . 2022;43(9):1262–1264	Quasi-experimental	"Dirty" surgical instruments (uncleaned), laboratory, United States	Instruments inoculated with test organisms with or without blood	Steam sterilization 270C for 4 min, ethylene oxide, hydrogen peroxide gas plasma	Effectiveness (MRSA, VRE, P aeruginosa, M terrae, G stearothermophilus/ B atrophaeus)	Steam sterilization is the most effective sterilization technology with the largest margin of safety, followed by ethylene oxide and hydrogen peroxide gas plasma.	IIB

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73	Almatroudi A, Tahir S, Hu H et al. Staphylococcus aureus dry-surface biofilms are more resistant to heat treatment than traditional hydrated biofilms. *J Hosp Infect* . 2018;98(2):161–167	Quasi-experimental	Laboratory setting, S. aureus was grown as both hydrated and dry-surface biofilm in the CDC biofilm generator	both biofilms were subjected to a range of temperatures in a hot-air oven (dry heat) and water bath or autoclave (wet heat)	no treatment	culture positivity after interventions - both dry and wet heat application to both hydrated and dry-surface biofilms	Following autoclaving samples were culture negative but 62-74% of bacteria in dry-surface biofilms remained alive as demonstrated by live/dead staining and confocal microscopy. Dry-surface biofilms subjected to autoclaving at 121degreeC for up to 30min recovered and released planktonic cells. Recovery did not occur following autoclaving for longer or at 134degreeC, at least during the time-period tested. Hydrated biofilm recovered following dry-heat treatment up to 100degreeC for 10min but failed to recover following autoclaving despite the presence of 43-60% live cells as demonstrated by live/dead staining. S. aureus dry-surface biofilms are less susceptible to killing by dry heat and steam autoclaving than hydrated biofilms, which are less susceptible to heat treatment than planktonic suspensions	IIA
74	Araújo PA, Mergulhão F, Melo L, Simões M. The ability of an antimicrobial agent to penetrate a biofilm is not correlated with its killing or removal efficiency. *Biofouling* . 2014;30(6):675–683	Quasi-experimental	biofilms of B. cereaus and P. fluorescens in a colony biofilm assay.	12 antimicrobial agents, including antibiotics and biocides	no treatment	culture positivity after treatment with four antimicrobial agents	Comparative analysis of the results obtained with colony biofilms and microtiter plate biofilms show that although extracellular polymeric substances and the biofilm structure are considered a determining factor in biofilm resistance, the ability of an antimicrobial agent to penetrate a biofilm is not correlated with its killing or removal efficiency.	IIB
75	Sheitoyan-Pesant C, Alarie I, Iorio-Morin C, Mathieu D, Carignan A. An outbreak of surgical site infections following craniotomy procedures associated with a change in the ultrasonic surgical aspirator decontamination process. *Am J Infect Contro* l. 2017;45(4):433–435	Case Report	n/a	n/a	n/a	n/a	An outbreak of surgical site infections that occurred in a tertiary care hospital in Quebec, Canada. This investigation revealed that a change in the sterilization process of the ultrasonic surgical aspirator may have caused this outbreak. It emphasizes the fact that the complex designs of surgical power tools may restrict access to cleaning and sterilization agents. Health care professionals should review manufacturers' assembly/disassembly instructions and sterilization/decontamination procedures before use of such tools.	VB
76	Lucas AD, Nagaraja S, Gordon EA, Hitchins VM. Evaluating device design and cleanability of orthopedic device models contaminated with a clinically relevant bone test soil. *Biomed Instrum Technol* . 2015;49(5):354–362	Organizational Experience	orthopedic devices used in the presence of bone cement during operative procedures	n/a	n/a	n/a	Models that were more complex retained significantly more bone debris than simpler designs. Model devices repeatedly soiled and cleaned 10 times retained significantly more bone debris than those soiled and cleaned once. Significantly more bone cement was retained in the more complex lumen structures. This information may be useful in designing reusable orthopedic devices, and other complex medical devices with lumens.	VC
77	Guideline for sharps safety. In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:935–958	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for perioperative sharps safety	IVA

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78	Alfa MJ. Biofilms on instruments and environmental surfaces: do they interfere with instrument reprocessing and surface disinfection? Review of the literature. *Am J Infect Control.* 2019;47(suppl):A39–A45	Literature Review	n/a	n/a	n/a	n/a	Although the evidence for exogenous infection transmission from sterilized surgical instruments is not as conclusive as for high level disinfected endoscopes, it still highlights the role that biofilm or retained secretions and tissue may play if cleaning is not effective.	VA
79	Lopes LKO, Costa DM, Tipple AFV et al. Complex design of surgical instruments as barrier for cleaning effectiveness, favouring biofilm formation. *J Hosp Infect.* 2019;103(1):e53–e60	Quasi-experimental	New flexible medullary reamers and depth gauges, Brazil	Manual cleaning, manual plus automated cleaning, steam sterilization	Rinsing in distilled water	ATP levels, microbial load, residual protein, microscopy	Soil and/or biofilms were evident on complex-design reusable surgical instruments after 20 cycles of contamination and reprocessing, even with reference standard cleaning methods.	IIA
80	Kremer TA, Carfaro C, Klacik S. Effects of time, temperature, and humidity on soil drying on medical devices. *Biomed Instrum Technol* . 2023;57(2):58–66	Quasi-experimental	Laboratory, United States	Time, temperature, and humidity variations on soil drying	Different time points, temperatures, and humidity levels	Soil solubility and retention	Soil drying after 8 hours significantly reduces solubility; higher temperatures (>22°C) and lower humidity (<50%) decrease solubility.	IIB
81	Hoover J, Drosnock MA, Carfaro C, Kremer TA. Cleaning challenges: can extended soil dry times be reversed? *Biomed Instrum Technol.* 2023;57(2):44–51	Quasi-experimental	Steel coupon and clamp contaminated with test soil and dried for 72 hours, Laboratory, United States	Soaking	Critical water, an alkaline enzymatic, a neutral pH detergent, three enzymatic detergents, and an enzymatic humectant foam spray	Soil remaining	Soaking with an alkaline cleaning agent as an additional step is effective when soil is dried on reusable medical devices, thus reversing the effect of an extended soil dry time.	IIB
82	Kimble A, Ratanski C, Kremer TA. Chemical changes over time associated with protein drying. *Biomed Instrum Technol.* 2023;57(2):52–57	Quasi-experimental	Three protein solutions, Laboratory, United States	Drying proteins for 48 hours	Initial time zero (wet condition)	Molecular weight distribution, UV absorbance, light-scattering signal	Protein solutions that have dried are less soluble and harder to clean.	IIC
83	Wulff BR, Lohse S, Tschoerner M. Influence of drying time on the removal of blood from medical devices. *J Hosp Infect* . 2024;152:156–163	Quasi-experimental	Test specimens contaminated with sheep's blood, Laboratory, Germany	Drying times of blood on test specimens	Different drying times (0, 30, 60, 90, 150, 300, 1440 min)	Residual protein measured visually and spectroscopically	Optimal cleaning results are achieved either immediately after contamination or between 3 and 24 hours after soiling.	IIC
84	*AAMI TIR109:2025; External Transport of Reusable Medical Devices for Processing* . Association for the Advancement of Medical Instrumentation; 2025	Consensus	n/a	n/a	n/a	n/a	Provides guidance for health care facilities and offsite reprocessing centers for the external transportation of processed medical devices between these facilities (e.g., from one health care facility to another, between offsite reprocessing center and health care facility). It provides guidance on maintaining the integrity of sterilized items and transport for contaminated and processed items.	IVC
85	Transporting infectious substances overview. US Department of Transportation. Pipeline and Hazardous Materials Safety Administration. Updated October 17, 2022. Accessed August 14, 2025. https://www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-overview	Regulatory	n/a	n/a	n/a	n/a	Department of Transportation guidance on transporting infectious substances.	n/a
86	*ASTM F1744-96(2024). Standard Guide for Care and Handling of Stainless Steel Surgical Instruments.* ASTM International; 2024	Consensus	n/a	n/a	n/a	n/a	International consensus standard that discusses care of stainless steel surgical instruments including cleaning, lubrication, and inspection.	IVC

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87	Guideline for sterile technique. In: *Guidelines for Perioperative Practice* . AORN Inc; 2025:1003–1048	Guideline	n/a	n/a	n/a	n/a	Evidence-based practice recommendations for sterile technique in the perioperative setting	IVA
88	Basile RJ, Kovach S, Drosnock MA. Guidelines for selecting a cleaning brush. *Biomed Instrum Technol* . 2019;53(suppl 2):49–54	Expert Opinion	n/a	n/a	n/a	n/a	Brushing is a mechanical action use to remove clinical soil from internal and external surfaces of medical devices during processing. Selecting and using the right burst is essential for effectiveness. The manufacturer may provide specifications for brush selection.	VB
89	Bronzatti JAG, Laranjeira PR, Bruna CQM, Graziano KU. The effect of brush motion and rinsing when manually cleaning cannulated medical devices. *AORN J* . 2020;111(5):508–514	Quasi-experimental	21 samples, 16fr clear polyvinyl chloride gastroduodenal catheters, laboratory, Brazil	Various cleaning procedures: (1) High-pressure water only (2) Back-and-forth brushing without brush rinsing (3) Back-and-forth brushing with brush rinsing (4) Helical spinning brushing without brush rinsing (5) Helical spinning brushing with brush rinsing	Positive control: No cleaning Negative control: Unused catheters	Amount of residual organic matter measured by adenosine triphosphate (ATP) testing and visual inspection for visible soil	Rinsing the brush during cleaning significantly decreased the amount of organic material remaining in the lumen. Helical spinning motion with brush rinsing was the most effective method, achieving a 98.9% reduction in ATP and no visible soil. Additional testing with a larger sample size is recommended to confirm these results.	IIC
90	Cao M, Qian C. The effects of perfusion device technology in the cleaning of luminal instruments. *Sterile Supply.* 2024;3(1):46–50	RCT	400 lumened surgical instruments, China	Flow water washing + ultrasonic cleaning + perfusion device	Conventional flow water washing + ultrasonic cleaning + manual cleaning process	Visual inspection, white brush, ATP fluorescence detector	Perfusion technology combined with manual cleaning significantly improves the cleaning quality of luminal instruments, accelerates turnover efficiency, and ensures surgical safety.	IC
91	Alfa MJ, Olson N. Comparison of washer-disinfector cleaning indicators: Impact of temperature and cleaning cycle parameters. *Am J Infect Control.* 2014;42(2):e23–e26	Quasi-experimental	One Miele G7883 washer-disinfector was tested for cleaning effectiveness in 15 different conditions	15 washer-disinfector cycles; one with optimal parameters and performance, and 14 with suboptimal enzymatic detergent, cleaning time, temperature, or inactive spray arms were evaluated	comparison among the three cleaning indicators: Pinnacle Monitor for Automated Enzymatic Cleaning Process (PNCL), Wash-Checks (WC), and TOSI	PNCL, TOSI, and WC cleaning indicators showed significantly more failures at 40 C compared with 60 C (100% vs 0% for PNCL, 17% vs 0% for TOSI, and 60% vs 22% for WC, respectively). There were significantly more failures at suboptimal temperatures with a 2- versus 4-minute cycle (100% vs 0% for PNCL, 17% vs 0% for TOSI, and 17% vs 0% for WC, respectively, for 40 C cycles)	Despite suboptimal cleaning cycles, all soiled tweezers looked clean. Conclusion All 3 cleaning indicators responded to suboptimal WD conditions; however, the PNCL was the most affected by alterations in the cycle conditions evaluated. In simulated use testing, cleaning indicators provided a more sensitive audit tool compared with visual inspection of soiled instruments after automated cleaning.	IIA
92	Guideline for environmental cleaning. In: *Guidelines for Perioperative Practice.* AORN Inc; 2025:197–226	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for environmental cleaning of the perioperative area	IVA

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93	Stjärne Aspelund A, Sjöström K, Olsson Liljequist B, Mörgelin M, Melander E, Påhlman LI. Acetic acid as a decontamination method for sink drains in a nosocomial outbreak of metallo-ß-lactamase-producing Pseudomonas aeruginosa. J Hosp Infect. 2016;94(1):13–20	Case Report	n/a	n/a	n/a	n/a	A nosocomial outbreak of Pae-MBL associated with hospital sink drains was investigated and to evaluate acetic acid as a decontamination method. Antibacterial and antibiofilm properties of acetic acid were evaluated in vitro. Pae-MBL-positive sinks were treated with 24% acetic acid once weekly and monitored with repeated cultures. Typing of clinical and sink drain isolates revealed identical or closely related strains to those in the outbreak. Pae-MBL biofilm was highly sensitive to acetic acid with a minimum biofilm eradication concentration of 0.75% (range: 0.19-1.5). Weekly treatment of colonized sink drains with acetic acid resulted in negative cultures and terminated transmission. Acetic acid is highly effective against Pae-MBL biofilms, and may be used as a simple method to decontaminate sink drains and to prevent nosocomial transmission.	VA
94	Smolders D, Hendriks B, Rogiers P, Mul M, Gordts B. Acetic acid as a decontamination method for ICU sink drains colonized by carbapenemase-producing Enterobacteriaceae and its effect on CPE infections. *J Hosp Infect* . 2019;102(1):82–88	Nonexperimental	sink drains in a single ICU department in Belgium	n/a	n/a	in-vitro growth of OXA-48; Carbapenemase-producing Enterobacteriaceae (CPE)	A variety of CPE strains, all carrying the OXA-48 resistance gene, were isolated from almost all sinks in patient rooms in the ICU. Decontamination of the sinks with 250 mL 25% acetic acid three times weekly was implemented. Sink drain colonization was followed up for six months thereafter. Both the number of CPE-colonized sinks and the number of patients colonized or infected with CPE decreased drastically, to the extent that the epidemic was considered to be eradicated. In-vitro growth of all isolates was inhibited by a concentration of acetic acid equal to or smaller than that used for decontamination. Epidemiological analysis demonstrated a positive and significant relationship between contaminated sinks and CPE acquisition of patients admitted to ICU rooms, indicating the importance of contaminated sinks as the environmental reservoir of the epidemic.	IIIA
95	Beni HH, Shafiei Z, Ghadami A. A comparative study of the manual, automated, and ultrasonic surgical-instrument cleaning methods. *J Iran Med Council* . 2022;5(3):486–493	Quasi-experimental	90 surgical instruments, Iran	Ultrasonic Cleaning	Manual cleaning, Automated cleaning	Presence of blood and protein residue on instruments	Ultrasonic cleaning was the most effective method for removing blood and protein residues from surgical instruments.	IIB
96	Kovach SM. Research: ensuring cavitation in a medical device ultrasonic cleaner. *Biomed Instrum Technol.* 2019;53(4):280–285	Quasi-experimental	4 products intended for testing cavitation in ultrasonic cleaners, United States	Manual shaking of jars with cleaning solution	n/a	Detection of cavitation (color change, soil removal)	Only Product A accurately detected the absence of cavitation. Products B, C, and D indicated cavitation presence despite no cavitation being present.	IIC
97	Di Blasio A, Barenghi L. Pitfalls of cleaning controls in ultrasonic washers. *Am J Infect Control.* 2015;43(12):1374–1375	Expert Opinion	n/a	n/a	n/a	n/a	A subjective assessment of solution turbidity, use of cleaning indicators, and visual inspection are the amin means of cleaning efficacy; strict guidelines an well-designed protocols and clear IFUs, and appropriate solutions and test soils are needed for correct ultrasonic washer use.	VA

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98	Yamashita K, Miyabe S, Yamashita T et al. Corrosion generation and cleaning effect on surgical instruments with attached radiofrequency identification tags in long-term usage. *Surg Infect (Larchmt)* . 2019;20(8):665–671	Quasi-experimental	94 surgical instruments with RFID tags, Japan	Various cleaning methods (Washer-Disinfector, ultrasonic, manual, thermostat chambers)	No cleaning	Microscopy, residual protein amount, corrosion observation	When WD is used properly, there is only a minor risk of residual protein, and corrosion does not occur even with long-term use.	IIB
99	Guideline for the safe use of surgical energy devices. In: *Guidelines for Perioperative Practice* . AORN Inc; 2026:143–168	Guideline	n/a	n/a	n/a	n/a	Provides evidence-based recommendations for electrosurgical safety in the operating room.	IVA
100	Zhang Y, Zhang Y, Wang Y, Yang L, Hu R. The packaging and clean method contribute to insulation failure of electrosurgical instruments. *Medicine (Baltimore)* . 2021;100(42):e27492	Quasi-experimental	740 reusable electrosurgical instruments, 200 rigid laparoscopes without failures, China	100 rigid laparoscopes which were packaged with appropriate fixing frames and loaded into a plastic basket with non-woven fabric cushions	100 rigid laparoscopes which were loaded into a plastic basket with non-woven fabric cushions directly	Insulation failures, conduction failures, short-circuits	Insulation failure was a wide problem of reusable electrosurgical instruments. Fixed packaging and mild cleaning procedures result in fewer damages to insulating property of reusable electrosurgical instruments.	IIB
101	Alfa MJ. Monitoring and improving the effectiveness of cleaning medical and surgical devices. *Am J Infect Control.* 2013;41(5 suppl):S56–S59	Expert Opinion	n/a	n/a	n/a	n/a	Key issues identified by monitoring cleaning efficacy include (a) automated cleaning methods are generally more reproduceable and require monitoring to evaluate cleaning functionality; (b) infection transmission can occur when residual clinical soil or biofilm are allowed to accumulate before sterilization; (c) monitoring cleaning provides a valuable tool for personnel education and compliance monitoring.	VA
102	Tosh PK, Disbot M, Duffy JM et al. Outbreak of Pseudomonas aeruginosa surgical site infections after arthroscopic procedures: Texas, 2009. *Infect Control Hosp Epidemiol* . 2011;32(12):1179–1186	Nonexperimental	outbreak at a single setting after arthroscopic procedures	n/a	n/a	organ space SSI due to P. aeruginosa	SSIs were likely related to surgical instrument contamination with P. aeruginosa during instrument reprocessing. Retained tissue in inflow/outflow cannulae and shaver handpieces could have allowed bacteria to survive sterilization procedures	IIIA
103	Ofstead CL, Smart AG, Holdsworth JE, Gantt BM, Lamb LA, Bush KM Jr. Unseen threats: lumens 2.0 study reveals the hidden challenges of cleaning lumened surgical instruments. *Am J Infect Contro* l. 2025;53(5):537–547	Organizational Experience	Large academic medical center, United States	n/a	n/a	Presence of visible soil or debris after cleaning	Cleaning according to manufacturer's instructions was not effective for lumened surgical instruments. Collaboration between infection prevention, sterile processing, and manufacturers is needed to improve processing outcomes.	VA
104	Hopkins KM, Adams SJ, Lamb LA, Smart AG, Ofstead CL. Beyond endoscopes: pilot study of surgical instrument lumen inspection. *Biomed Instrum Technol* . 2024;58(1):25–33	Organizational Experience	18 surgical instruments (10 suctions, 8 shavers), United States	Borescope inspections	n/a	Presence of internal features, debris, discoloration, and effectiveness of recleaning	Visual inspection can identify instruments with damage, residual soil, and retained debris that could otherwise harm patients, but it requires substantial time, training, and support from stakeholders.	VA
105	Li X, Yang M, Yang J, Shi Y, Wei X. Monitoring and analysis of the cleaning effect of spinal surgical instruments by visual track viewer. *Sterile Supply* . 2024;3(2):62–66	Quasi-experimental	226 luminal spinal instruments, China	Manual cleaning plus mechanical cleaning	Mechanical cleaning only	Visual track viewer (blood, stain, foreign body, tissue residue)	Manual cleaning plus mechanical cleaning significantly improves pollutant clearance rates compared to mechanical cleaning alone.	IIC
106	Santos RKD, Pozzer CE, Rabaioli CM, Souza R, Santos SGRD, Caregnato RCA. Central sterile services department: screening of automated cleaning in liposuction cannulae. *Rev Gaucha Enfermagem* . 2022;43:e20210057	Nonexperimental	14 liposuction cannulas (4mm) cleaned by automated methods (ultrasonic), Brazil	n/a	n/a	Culture	It is not possible to ensure the cleaning efficacy of automated cleaning of 4 mm liposuction cannulas, especially due to the conformation of the material with internal spaces.	IIIC

REF#	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	SCORE
107	Alfa MJ. Medical instrument reprocessing: current issues with cleaning and cleaning monitoring. *Am J Infect Contro* l. 2019;47(suppl):A10–A16	Literature Review	n/a	n/a	n/a	n/a	There has been a paradigm shift in reprocessing of medical devices, with increased emphasis on a quality management systems approach that requires validated cleaning instructions from manufacturers and ongoing monitoring by reprocessing personnel to ensure adequacy of cleaning.	VA
108	Dolci ME, Lobo RD, Nunes JA et al. Evaluation of cleaning process efficacy of instruments for robotic surgery using the adenosine triphosphate test. *Surgery.* 2023;174(2):296–300	Nonexperimental	279 EndoWrist instruments from 65 robotic surgeries; Brazil	n/a	n/a	Visual inspection and ATP bioluminescence test	Manual plus automated cleaning processes reduced bioburden effectively. Instruments can be safely reprocessed 9 times. Monopolar instruments are the easiest to clean.	IIIB
109	Pelzer RJ, van der Zwet WC, Eggen MMEG, Beard A, Savelkoul PHM, Dirks JAMC. Evaluation of microbial occurrence in reusable robotic instruments for minimally invasive surgery: a pilot study. PLoS One. 2024;19(4):e0300355.	Quasi-experimental	20 robotic instruments, Netherlands	Cleaning, disinfection, and sterilization (CDS) procedure	4 robotic instruments tested <1 hour after patient use	Presence of viable microorganisms	The CDS procedure was sufficient for safe reuse of robotic instruments in up to 10 patients.	IIC
110	Saito Y, Yasuhara H, Murakoshi S, Komatsu T, Fukatsu K, Uetera Y. Novel concept of cleanliness of instruments for robotic surgery. *J Hosp Infect.* 2016;93(4):360–361	Expert Opinion	n/a	n/a	n/a	n/a	Robotic instruments are difficult to clean and research on cleanability of robotic instruments on residual clinical soils supports this claim. Measurement of residual protein could estimate how difficult it is to clean an instrument.	VA
111	Saito Y, Yasuhara H, Murakoshi S, Komatsu T, Fukatsu K, Uetera Y. Challenging Residual Contamination of Instruments for Robotic Surgery in Japan. *Infect Control Hosp Epidemiol.* 2017;38(2):143–146.	Nonexperimental	Robotic instruments after clinical use	n/a	n/a	presence of residual protein	The researches described complete removal of residual protein from robotic instruments used in operative procedures as "virtually impossible" and calls for establishing a new standard for cleaning using a novel classification according to the structural complexity of surgical instruments.	IIIB
112	Fitts LN, Yegge J, Goris A, Vinson S, Dubberke E. How clean is clean enough? An observational pilot study to assess central sterilization processing efficacy with adenosine triphosphate levels. *Am J Infect Control.* 2020;48(4):420–422	Organizational Experience	Community hospital, United States	n/a	n/a	ATP	The central sterilization processing department identified difficult to clean instruments for hip, spinal fusion, and colon procedures. Only 1 of the 44 instruments that went through the washer did not pass ATP testing. Compliance with point of use spray treatment was 51%. The researchers determined that the facility's processes were adequate for the instruments tested.	VB
113	Kurley B. ATP testing: an anecdotal look at its use in an office-based plastic surgery setting. *Plast Surg Nurs.* 2014;34(4):167–170	Organizational Experience	one instrument (the one considered most difficult to clean) from each surgical case on each day of surgery during the test period for a total of 1,500 test points	n/a	n/a	n/a	Testing for the presence of adenosine triphosphate (ATP) on a cleaned instrument can help determine if it meets cleanliness requirements for sterilization. A program was piloted by using a commercial ATP testing system. In this article, the experience with the evaluation of available ATP testing systems, the implementation processes we used, and conclusions drawn from our procedures and results are described.	VA

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114	Kremer TA, Kimble A, Ratanski C. Improving protein assay methods to more accurately assess medical device cleanliness. *Biomed Instrum Technol* . 2023;57(4):122–128	Quasi-experimental	Laboratory, United States	Variation of the micro-bicinchoninic acid (BCA) assay	Standard addition method, increased well volume, changed working reagent ratio	Protein detection	These experiments offer improvements to the protein residual detection method using the micro BCA. This work contributes to knowledge regarding the appropriate use of analytical methods to measure device cleanliness. These protein method improvements may be used in protein residual method validations that support cleaning efficacy testing for reusable medical devices, as well as be included in associated standards.	IIB
115	Kremer TA, Patel A, Summers C, Quin M, Lemons K, McDonnell G. Protein residuals on reusable medical devices and patient safety impact. *Zentr Steril* . 2019;27(3):178–183	Nonexperimental	Laboratory, United States	n/a	4 human blood proteins (albumin, horseradish peroxidase, cathespsin G, cobra venom factor)	Cytotoxicity score based on ISO 10993-5	Acceptable protein level for cleaning efficacy studies is in the 3-6.4 µg/cm² range. Residual protein remaining on a device before patient use presents several patient safety concerns, including preventing effective disinfection or sterilization process, adverse immune response to residual protein, and risk of prion contamination and transmission.	IIIB
116	Kremer TA, Felgar J, Rowen N, McDonnell G. Validation of the device feature approach for reusable medical device cleaning evaluations. *Biomed Instrum Technol.* 2023;57(4):143–152	Quasi-experimental	Laboratory, Ireland and United States	Device feature approach for cleaning validations	Compendial method (whole device approach)	Residual protein concentration	The device feature approach is more conservative and effective for validating cleaning requirements of reusable medical devices compared to the compendial method.	IIB
117	Kremer T, Rowan NJ, McDonnell G. A new quantitative method for determining patient risk for reusable medical device categorization based on using and interpreting Kremer's cleaning classification system. *J Hosp Infect.* 2024;155:234–247	Quasi-experimental	23 device features, Laboratory, Ireland and United States	Cleaning process with and without brush/flush steps depending on protein values	Soil drying for various times (2hr, 3hr, 72hr)	Point of failure for fluid dynamics (extraction efficiency) and soil retention	Kremer's cleaning classification system effectively categorizes reusable medical devices based on cleaning challenges and patient risk.	IIB
118	Chang DF, Mamalis N; Ophthalmic Instrument Cleaning and Sterilization Task Force. Guidelines for the cleaning and sterilization of intraocular surgical instruments. *J Cataract Refract Surg* . 2018;44(6):765–773	Guideline	n/a	n/a	n/a	n/a	These Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments were written by the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force, comprised of representatives of the American Society of Cataract and Refractive Surgery, the American Academy of Ophthalmology, and the Outpatient Ophthalmic Surgery Society. These consensus subspecialty guidelines include evidence-based recommendations regarding issues that may be unique to the cleaning and sterilization of intraocular instrumentation.	IVB
119	Mamalis N. Toxic anterior segment syndrome: role of enzymatic detergents used in the cleaning of intraocular surgical instruments. *J Cataract Refract Surg* . 2016;42(9):1249–1250	Expert Opinion	n/a	n/a	n/a	n/a	The OICS Task Force, in conjunction with the FDA, concluded that the best way to eliminate the potential risk for TASS with the use of enzymatic detergents is to have ophthalmic instrument manufacturer's develop validated alternative methods of decontamination that do not require enzymatic detergents. This group has put out a formal recommendation to the ophthalmic instrument manufacturers to help devise and validate methods to clean and decontaminate ophthalmic surgical instruments without the use of enzymatic detergents.	VA

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120	Shorstein NH, Lucido C, Carolan J, Liu L, Slean G, Herrinton LJ. Failure Modes and Effects Analysis of bilateral same-day cataract surgery. *J Cataract Refractive Surg.* 2017;43(3):318–323	Organizational Experience	4754 procedures involving eyes	n/a	n/a	n/a	Potential failure modes and recommended actions in bilateral same-day cataract surgery were determined using an FMEA. These findings might help improve the reliability and safety of bilateral same-day cataract surgery based on current evidence and standard	VA
121	Mamalis N, Edelhauser HF. Enzymatic detergents and toxic anterior segment syndrome. *Ophthalmology.* 2013;120(3):651–652	Expert Opinion	n/a	n/a	n/a	n/a	Letter to the editor: The results of this study [Leder et al entitled "An Investigation of Enzymatic Detergents as a Potential Cause of Toxic Anterior Segment Syndrome"] actually provide additional support for the role of enzymatic detergents as a potential cause for TASS.	VA
122	Tamashiro NSM, Souza RQ, Gonçalves CR et al. Cytotoxicity of cannulas for ophthalmic surgery after cleaning and sterilization: evaluation of the use of enzymatic detergent to remove residual ophthalmic viscosurgical device material. *J Cataract Refract Surg* . 2013;39(6):937–941	Nonexperimental	30 reusable 25-gauge injection cannulas, 20.0 mm in length, whose lumens were filled with an OVD solution for 50 minutes	n/a	n/a	Presence of OVD solution after processing	The cleaning protocol used in this study removed residues of OVD solution and enzymatic detergent as shown by the lack of cytotoxicity of all sample extracts. This cleaning protocol has the potential to minimize the occurrence of toxic anterior segment syndrome associated with residues of OVD solutions and enzymatic detergents.	IIIC
123	Zhou W, Ye C, Huang X et al. Efficacy of cleaning methods for ophthalmic microscopic instruments: a comparison study. *AORN J.* 2020;112(2):112–121	RCT	320 titanium-alloy instruments and 320 stainless-steel instruments, China	Four cleaning procedures: (1) water + multi-enzyme detergent, (2) water + alkaline detergent, (3) multi-enzyme detergent + alkaline detergent, (4) alkaline detergent + multi-enzyme detergent	Comparison of cleaning procedures	ATP	The alkaline detergent + multi-enzyme detergent cleaning procedure was the most effective for both titanium-alloy and stainless-steel instruments contaminated with blood and silicone oil.	IB
124	Tsaousis KT, Werner L, Reiter N et al. Comparison of different types of phacoemulsification tips. II. Morphologic alterations induced by multiple steam sterilization cycles with and without use of enzyme detergents. *J Cataract Refract Surg* . 2016;42(9):1353–1360	Quasi-experimental	John A. Moran Eye Center, Salt Lake City, Utah, USA - 2 types of reusable phacoemulsification needles	each phacoemulsification needle was cleaned with detergent followed by rinsing with sterile water or no rinsing between steam sterilization cycles	no rinsing with sterile water	presence of residues measured by scanning electron microscopy and energy-dispersive x-ray spectroscopy	rinsing the phaco tips significantly reduced the size and number of residues after use of enzymatic detergents; however detergent residues were detected even after thorough rinsing with sterile water	IIB
125	Choi JH, Cho YS, Lee JW, Shin HB, Lee IK. Bacterial contamination and disinfection status of laryngoscopes stored in emergency crash carts. *J Prev Med Pub Health.* 2017;50(3):158–164	Nonexperimental	148 reusable laryngoscope handles and 71 reusable laryngoscope blades deemed ready for patient use	n/a	n/a	presence of microbial growth on blood auger after 18 hour incubation period	One or more species of bacteria were isolated from 4 (5.6%) handle tops, 20 (28.2%) handles with knurled surfaces, and 27 (18.2%) blades. No significant differences were found in microbial contamination levels on the handle tops and blades between the two hospitals and two areas according to the frequency of intubation attempts. However, significant differences were found between the two hospitals and two areas in the level of microbial contamination on the handles with knurled surfaces ($p<0.05$). Protocols and policies must be reviewed to standardize procedures to clean and disinfect laryngoscope blades and handles; handles should be re-designed to eliminate points of contact with the blade; and single-use, one-piece laryngoscopes should be introduced.	IIIA

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126	Negri de Sousa AC, Levy CE, Freitas MI. Laryngoscope blades and handles as sources of cross-infection: an integrative review. *J Hosp Infect* . 2013;83(4):269–275	Literature Review	n/a	n/a	n/a	n/a	There are contradictions in the published literature included in this review. Important gaps warrant further study. The following are considered necessary: (i) a review of processing protocols for laryngoscope blades and handles, considering the possible presence of blood and organic matter and potentially pathogenic microorganisms; (ii) investigational studies that consider pathogenic agents such as mycobacteria, human immunodeficiency virus, hepatitis B and C in laryngoscope blades and cables; (iii) revision of the classification of the potential risks of laryngoscope blades and handles for both the patient and the health team handling this equipment.	VA
127	Sherman JD, Raibley LA IV, Eckelman MJ. Life cycle assessment and costing methods for device procurement: comparing reusable and single-use disposable laryngoscopes. *Anesth Analg.* 2018;127(2):434–443	Nonexperimental	Life Cycle Assessment (LCA) comparing single use to multiuse laryngoscope blades and handles	n/a	n/a	comparison of CO2 equivalents per use	Environmental impacts of reusable laryngoscope handles and blades are less than SUD alternatives from an environmental perspective, with HLD the least polluting reprocessing method. Selection and use of these should be balanced with other factors including infection prevention, performance, and cost of ownership.	IIIA
128	Van Wicklin SA. Contamination and disinfection of rigid laryngoscopes: a literature review. *AORN J.* 2019;110(1):49–59.	Literature Review	n/a	n/a	n/a	n/a	This article reviews current literature about the contamination of laryngoscope blades and handles, disinfection practices for laryngoscope blades and handles, and environmental effects and costs of reusable and single-use laryngoscopes. This review shows that inadequately processed rigid laryngoscopes may have the ability to transmit infections to patients and health care personnel. Although the laryngoscope handle has been considered a noncritical item that contacts only intact skin, health care team members should consider both the laryngoscope blade and handle as semi critical items and process them by high-level disinfection (HLD) or steam sterilization according to manufacturer's instructions. The fewest environmental effects occur when a reusable stainless-steel laryngoscope is processed by HLD. Laryngoscope costs are lower for processing reusable laryngoscope handles and blades by HLD and highest for single-use laryngoscopes. Evidence-based guidelines are needed to specify and standardize best practices for processing rigid laryngoscopes.	VA
129	Nielsen SW, Stevens JR, Stevens GJ, Patel J, Eller RL. Mandated wrapping of airway cart instruments: limited access without the intended safety benefits. *Laryngoscope.* 2019;129(3):715–719	Nonexperimental	retrospective review of 200 patient records at one military medical center in Southwestern US	n/a	n/a	length of stay, airway infections, patient death, time for clinicians to locate instruments in the emergency airway cart	Each group had a total of four airway infections and neither had any deaths. The average length of hospital stay was 0.36 days for the unpackaged period and 0.44 days from the packaged period. None of these variables reached statistical significance. The average time to find and set out the correct instruments for the two groups was 46.6 and 95.5 seconds for the unpackaged and packaged airway carts, respectively (P = .004)	IIIA

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130	Rutala WA, Weber DJ: Society for Healthcare Epidemiology of America. Guideline for disinfection and sterilization of prion-contaminated medical instruments. *Infect Control Hosp Epidemiol.* 2010;31(2):107–117	Guideline	n/a	n/a	n/a	n/a	CDC guidance on disinfection and sterilization of prion-contaminated medical instruments.	IVA
131	*WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies: Report of a WHO Consultation Geneva, Switzerland, 23-26 March 1999.* World Health Organization; 2000. Accessed August 15, 2025	Guideline	n/a	n/a	n/a	n/a	World Health Organization guidelines for prevention of transmissible spongiform encephalopathies including CJD	IVA
132	Infection control for CJD. Centers for Disease Control and Prevention. May 13, 2024. Accessed August 15, 2025. https://www.cdc.gov/creutzfeldt-jakob/hcp/infection-control/index.html	Expert Opinion						VA
133	*WHO Tables on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies.* World Health Organization; 2010. Accessed August 15, 2025. https://cdn.who.int/media/docs/default-source/biologicals/blood-products/document-migration/tablestissueinfectivity.pdf	Guideline	n/a	n/a	n/a	n/a	World Health Organization infectivity tables: transmissible spongiform encephalopathies	IVA
134	Thomas JG, Chenoweth CE, Sullivan SE. Iatrogenic Creutzfeldt-Jakob disease via surgical instruments. *J Clin Neurosci.* 2013;20(9):1207–1212	Case Report	n/a	n/a	n/a	n/a	Scenario modeling predicts that after six cycles of instrument use with conventional cleansing following an index patient, other patients are highly unlikely to be at risk for iatrogenic CJD. Despite its rarity, the threat of iatrogenic CJD transmission via contaminated instruments poses tremendous challenges to neurosurgeons. Basic prevention strategies should be employed for patients with suspected CJD, including use of disposable instruments where possible and quarantining non-disposable instruments until the diagnosis is ascertained, or using special instrument reprocessing methods if CJD is suspected.	VA
135	*Reducing the Risk of Transmission of Creutzfeldt–Jakob Disease (CJD) from Surgical Instruments Used for Interventional Procedures on High-Risk Tissues* . NICE. January 22 , 2020. Accessed August 15, 2025. https://www.nice.org.uk/guidance/ipg666/resources/reducing-the-risk-of-transmission-of-creutzfeldtjakob-disease-cjd-from-surgical-instruments-used-for-interventional-procedures-on-highrisk-tissues-pdf-1899874227866821	Guideline	n/a	n/a	n/a	n/a	NICE guideline for reduction of procedural (surgical) CJD transmission risk	IVA

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136	Fichet G, Antloga K, Comoy E, Deslys JP, McDonnel G. Prion inactivation using a new gaseous hydrogen peroxide sterilisation process. *J Hosp Infect.* 2007;67(3):278–286	Quasi-experimental	hamster-adapted scrapie strain 263 K; bovine spongiform encephalopathy strain adapted to mice 6PB1 strain and mice overexpressing murine PrP - TGB1	In-vitro suspension studies using 263 K and 6PB1 strains - liquid hydrogen peroxide at 0.2, 3, 30, or 60% were mixed 4:1 with 20% brain homogenate . In-vivo study of gaseous hydrogen peroxide using stainless steel wires contaminated with prion-brain homogenates in plastic plates in a gas sterilization chamber with about 2mg/L VHP concentration	comparison of extent of clumping suggesting inactivation	presence of clumping after treatment to suggest inactivation	Low-temperature hydrogen peroxide gas process may be a useful technology for reducing the risks associated with prion-contaminated devices and other surfaces. More study is needed.	IIB
137	Yan ZX, Stitz L, Heeg P, Pfaff E, Roth K. Infectivity of prion protein bound to stainless steel wires: a model for testing decontamination procedures for transmissible spongiform encephalopathies. *Infect Control Hosp Epidemiol.* 2004;25(4):280–283	Quasi-experimental	197 mice	wires exposed to infected brain homogenate and divided into groups A, B, , D, E - each with different processing protocols including enzymatic detergents, OPA, VHP, peracetic acid, alkaline detergent (pH 11), and steam sterilization	comparison of survival	hamster alive at 18 months after implantation of inoculated wires	(1) Treatment of wires with an alkaline detergent at a pH of 11 shows significant reduction of infectivity, independent of the procedure (disinfection or sterilization) that follows. (2) Steam sterilization at 134°C for 18 minutes in combination with initial enzymatic cleaning does not result in the inactivation of the prion proteins. (3) Steam sterilization at 134°C for 18 minutes without initial enzymatic treatment results in much longer survival times of the animals. (4) Sterilization with the Sterrad system seems to have an effect similar to that of steam sterilization. (5) Highly concentrated (59%) hydrogen peroxide shows high efficacy in the inactivation of prion proteins	IIB
138	Rogez-Kreuz C, Yousfi R, Soufflet C et al. Inactivation of animal and human prions by hydrogen peroxide gas plasma sterilization. *Infect Control Hosp Epidemiol.* 2009;30(8):769–777	Quasi-experimental	Syrian golden hamsters officially registered for experimental prion studies on rodents (n=487); 60 were controls	wires exposed to infected brain homogenate and divided into 23 groups of inactivation protocols using hydrogen peroxide (liquid or gaseous), enzymatic detergents, alkaline detergents, steam sterilization cycles or VHP sterilization cycles - combined or alone	negative central (no exposure to infected brain homogenate) and positive controls	sick hamsters, hamster death; western blot analysis	Gaseous or vaporized hydrogen peroxide can inactivate prions on the surfaces of medical devices. However, the efficacy of this method depends on the conditions used, especially the concentration of hydrogen peroxide.	IIB
139	Secker TJ, Hervé R, Keevil CW. Adsorption of prion and tissue proteins to surgical stainless steel surfaces and the efficacy of decontamination following dry and wet storage conditions. *J Hosp Infect.* 2011;78(4):251–255	Quasi-experimental	316 surgical stainless steel tokens	laboratory inoculation of stainless steel with ME7-infected brain homogenate, left to dry in in dry versus moist conditions for 0-120 minutes	dry versus moist conditions after contamination	residual contamination after cleaning	longer dry times increased protein and prion amyloid adsorption and affected cleaning efficacy; the moist environment post-contamination significantly reduced the attachment of both protein and amyloid to the stainless steel surface.	IIB

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140	Smith A, Winter S, Lappin D et al. Reducing the risk of iatrogenic Creutzfeldt-Jakob disease by improving the cleaning of neurosurgical instruments. *J Hosp Infect.* 2018;100(3):e70–e76	Nonexperimental	Two instrument protein quantification methods: one based on the International Standard (15883 series) using sodium dodecyl sulphate elution and ortho-phthalaldehyde reaction, and a second in-situ protein fluorescence detection system (ProReveal) providing results per instrument side. In-vitro investigation of the efficacy of some commercial and in-house pre-clean wetting agents was undertaken using artificial test soil and stainless steel discs under standard conditions.	n/a	n/a	In-vivo evaluation of residual protein after cleaning on craniotomy sets	low in-situ protein levels on neurosurgical instruments and the beneficial effects of keeping instruments moist, other cleaning critical-control points such as instrument loading patterns should also be monitored	IIIA
141	Search for registered pesticide products: is your product registered? US Environmental Protection Agency. February 13 , 2025. Accessed August 15, 2025. https://www.epa.gov/safepestcontrol/search-registered-pesticide-products	Regulatory	n/a	n/a	n/a	n/a	EPA registered pesticide search website	n/a
142	McDonnell G, Dehen C, Perrin A et al. Cleaning, dinsinfection and sterilization of surface prion contamination. *J Hosp Infect.* 2013;85(4):268–273	Quasi-experimental	stainless steel wires contaminated with infected brain homogenate; hamsters	In vivo surface testing after various cleaning and sterilization combinations	positive controls	prion inactivation; hamster transmission or death	Prion decontamination is affected by the full reprocessing cycle used on contaminated surfaces. The correct use of defined cleaning, disinfection and sterilization methods as tested in this report in the scrapie infectivity assay can provide a standard precaution against prion contamination.	IIA
143	Kampf G, Jung M, Suchomel M, Saliou P, Griffiths H, Vos MC. Prion disease and recommended procedures for flexible endoscope reprocessing - a review of policies worldwide and proposal for a simplified approach. *J Hosp Infect* . 2020;104(1):92–110	Literature Review	n/a	n/a	n/a	n/a	It was postulated that current decontamination procedures, combined with immediate processing of surgical instruments, have the potential to be highly effective alone at reducing the risk of surgical transmission of CJD.	VA
144	Schmitt A, Westner IM, Reznicek L, Michels W, Mitteregger G, Kretzchmar HA. Automated decontamination of surface-adherent prions. *J Hosp Infect* . 2010;76(1):74–79	Quasi-experimental	Tga20 mice; stainless steel wires	Automated washer-disinfector processes (2)	compared routine alkaline disinfection process in washer-disinfector with a specifically-developed process for prion decontamination	reduction of surface-adherent prion infectivity of >7 log units	Process B, described in the article lasting 10 minutes longer than the standard cycle, was found to be highly pion effective compared with standard alkaline cleaning.	IIA

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145	Fichet G, Comoy E, Duval C et al. Novel methods for disinfection of prion-contaminated medical devices. *Lancet.* 2004;364(9433):521–526	Quasi-experimental	hamsters; stainless steel wires contaminated with brain homogenate	Standard chemical decontamination methods (NaOH 1N, NaOCl 20 000 ppm) and autoclaving in water at 134°C reduced infectivity by>5·6 log 10 lethal doses; autoclaving without immersion was somewhat less effective (4–4·5 log reduction). Three milder treatments, including a phenolic disinfectant, an alkaline cleaner, and the combination of an enzymatic cleaner and vaporized hydrogen peroxide (VHP) were also effective. VHP alone, which can be compatible with electronic components, achieved an approximately 4·5 log reduction in infectivity (equivalent to autoclaving without water immersion)	positive controls	prion inactivation	Alternative decontamination procedures are proposed to ensure the safety of medical and surgical instruments as well as surfaces that cannot withstand the currently recommended prion inactivation procedures	IIB
146	Heinzer D, Avar M, Pfammatter M et al. Advancing surgical instrument safety: a screen of oxidative and alkaline prion decontaminants using real-time quaking-induced conversion with prion-coated steel beads as surgical instrument mimetic. *PLoS One.* 2024;19(6):e0304603	Quasi-experimental	Approximately 70 different formulations, Laboratory, Switzerland	Screening of oxidative and alkaline prion decontaminants using TESSA	NaOH, ddH2O	Prion inactivation efficacy, prion titer reduction	TESSA is effective for rapid screening of prion-inactivating detergents. A hypochlorite-based formulation was identified as the most efficient prion decontaminant. Alkaline and oxidative formulations are promising for reducing prion transmission risk.	IIA
147	Belondrade M, Nicot S, Beringue V, Coste J, Lehmann S, Bougard D. Rapid and highly sensitive detection of variant Creutzfeldt-Jakob disease abnormal prion protein on steel surfaces by protein misfolding cyclic amplification: application to prion decontamination studies. *PLoS One.* 2016;11(1):e0146833	Nonexperimental	single steel wire over 2 weeks	n/a	n/a	protein and prion (Surf-PMCA) adsorption of minute quantities of human vCJD or ovine scrapie PrPTSE	Surf-PMCA can be used as a rapid and ultrasensitive assay for the detection of human vCJD PrPTSE adsorbed onto a metallic surface, therefore facilitating the development and validation of decontamination procedures against human prions.	IIIA
148	Hervé RC, Hedges J, Keevil CW. Improved surveillance of surgical instruments reprocessing following the variant Creutzfeldt-Jakob disease crisis in England: findings from a three-year survey. *J Hosp Infect.* 2021;110:15–25	Nonexperimental	Test soil and tissue from mice, Laboratory, United Kingdom	n/a	5 tests in 2 different automated washer-disinfectors	Microscopy	Microscopic levels of proteins remain on many reprocessed instruments. The impact most of these residues, potentially including prions, may have on subsequent patients after sterilization remains debatable. Improving surveillance capability in sterile services departments can support decision making and raise the standards of surgical instruments reprocessing.	IIIB
149	Secker TJ, Leighton TG, Offin DG, Birkin PR, Hervé RC, Keevil CW. A cold water, ultrasonically activated stream efficiently removes proteins and prion-associated amyloid from surgical stainless steel. *J Hosp Infect.* 2020;106(4):649–656	Quasi-experimental	Surgical stainless steel tokens contaminated with prion-infected brain homogenates, Laboratory, United Kingdom	Ultrasonically activated, cold water stream for 5 and 10 seconds	Untreated contaminated tokens	Residual protein and prion-associated amyloid quantified using microscopy and immunoblotting	Ultrasonically activated stream efficiently removes prion proteins, suggesting it could improve decontamination practices and reduce hospital-acquired infections.	IIC

REF#	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	SCORE
150	Schwenke KA, Wagenführ K, Thanheiser M, Beekes M. Kinetics of the reduction of Creutzfeldt-Jakob disease prion seeding activity by steam sterilization support the use of validated 134 °C programmes. *J Hosp Infect.* 2023;132:125–132	Quasi-experimental	Brain tissue samples from Syrian hamsters and humans, Laboratory, Germany	Steam sterilization at 134°C for various holding times	Untreated brain homogenates	Residual prion seeding activity measured by protein misfolding cyclic amplification	Steam sterilization at 134°C for 5 minutes substantially reduces prion seeding activity, provided thorough cleaning and no fixating chemical disinfection prior to sterilization.	IIB
151	Belay ED, Blase J, Sehulster LM, Maddox RA, Schonberger LB. Management of neurosurgical instruments and patients exposed to Creutzfeldt-Jakob disease. *Infect Control Hosp Epidemiol.* 2013;34(12):1272–1280	Literature Review	n/a	n/a	n/a	n/a	There were 19 incidents of patient exposure to potentially CJD-contaminated instrument reported to the CDC. Neurosurgical instruments used for treatment of patients with suspected or diagnosed CJD should be promptly identified and decontaminated according to recommended protocols.	VA
152	López FJG, Ruiz-Tovar M, Almazán-Isla J, Alcalde-Cabero E, Calero M, de Pedro-Cuesta J. Risk of transmission of sporadic Creutzfeldt-Jakob disease by surgical procedures: systematic reviews and quality of evidence. *Euro Surveill.* 2017;22(43):16–00806	Systematic Review	n/a	n/a	n/a	n/a	The association between surgery and sporadic CJD remains uncertain. Measures currently recommended for preventing CJD transmission should be strongly maintained.	IIIA
153	Smyth EG, Farrell M, Healy DG et al. Managing the consequences of neurosurgical intervention in a patient with previously undiagnosed Creutzfeldt-Jakob disease. *Infect Control Hosp Epidemiol.* 2014;35(7):907–908	Case Report	information on past CJD exposure incidents reported to the Centers for Disease Control and Prevention (CDC)	n/a	n/a	Nineteen incidents of patient exposure to potentially CJD-contaminated instruments were reported to the CDC, including 17 that involved intracranial procedures and 2 that involved ophthalmologic procedures. In more than 50% of incidents, the neurosurgical procedures were performed for diagnostic work up of the index patients. At least 12 of the hospitals had multiple neurosurgical sets, and the CJD-contaminated instruments could not be identified in 11 of 19 hospitals. In 12 of 15 hospitals with neurosurgical incidents, a decision was made to notify patients of their potential exposure.	Neurosurgical instruments used for treatment of patients with suspected or diagnosed CJD or patients whose diagnosis is unclear should be promptly identified and sterilized using recommended CJD decontamination protocols. Inability to trace instruments complicates appropriate management of exposure incidents. The feasibility of instituting instrument tracking procedures should be considered.	VA
154	Brown P, Farrell M. A practical approach to avoiding iatrogenic Creutzfeldt-Jakob disease (CJD) from invasive instruments. *Infect Control Hosp Epidemio* l. 2015;36(7):844–848	Case Report	n/a	n/a	n/a	n/a	Potential Creutzfeldt-Jakob disease instrument-contamination events continue to occur, causing widespread hospital and patient concern. We propose the use of a combination of diagnostic tests (ie, spinal fluid for 14-3-3 protein or nasal brushing for misfolded prion protein) and instrument handling procedures (ie, using a regional set of dedicated instruments), which if applied to all patients admitted with symptoms of either dementia or cerebellar disease, should eliminate the risk of iatrogenic instrument infection.	VA
155	29 CFR 1910.1200: hazard communication. Code of Federal Regulations. Accessed September 22, 2025. https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-Z/section-1910.1200	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations (law) regarding toxic and hazardous substances. OSHA	n/a

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156	Ofstead CL, Smart AG, Hopkins KM, Lamb LA, Daniels FE, Berg DS. Improving mastery and retention of knowledge and complex skills among sterile processing professionals: a pilot study on borescope training and competency testing. *Am J Infect Control* . 2023;51(6):624–632	Quasi-experimental	9 certified sterile processing employees, United States	Training model including pre-testing, lectures, hands-on practice, structured homework, and an online booster session	Pre and post training	Test scores, satisfaction, and confidence levels	This study demonstrated effectiveness and clinical relevance of a new, evidence-based model for training sterile processing professionals that incorporated pretesting, lectures, hands-on practice, a training booster, and post-testing to enhance learning. This model may be applicable to other complex skills necessary for infection prevention and patient safety.	IIC
157	Patel J, Gimeno Ruiz de Porras D, Mitchell LE et al. Cleaning tasks and products and asthma among health care professionals. *J Occup Environ Med.* 2024;66(1):28–34	Nonexperimental	9914 health care workers in Texas, United States	n/a	Cleaning tasks and products (ebuilding surface cleaning, ortho-phthalaldehyde, bleach/quaternary compounds, sprays)	Prevalence of physician-diagnosed asthma, work-exacerbated asthma, new-onset asthma, and bronchial hyperresponsiveness symptoms.	Prevalence of asthma/bronchial hyperresponsiveness seems unchanged; associations of new-onset asthma with surface cleaning exposures remained, decreased for instrument cleaning.	IIIB
158	Sweet W, Snyder D, Raymond M. Design and implementation of the infection prevention program into risk management: managing high level disinfection and sterilization in the outpatient setting. *J Healthc Risk Manag.* 2020;40(1):44–49	Organizational Experience	33 outpatient clinics in San Diego County, United States	n/a	n/a	n/a	Designing and integrating an Infection Prevention program into the Risk Management Department presented challenges, especially with the magnitude of devices and lack of standardization. Key components included: capturing accurate system-wide inventory of devices, hiring sterile processing expert, engaging support from senior leadership, adhering to rigorous auditing processes, and establishing staff competency training structure. Outcomes included: identification of high-risk practices with immediate resolution, increase in average clinic compliance with standards from 88% to 99%, elimination of 71% of scope reprocessing and 39% of instrument sterilization by clinic staff with allocation to central sterile processing departments, and development of a staff competency training structure.	VA
159	Alfred M, Catchpole K, Huffer E, Fredendall L, Taaffe KM. Work systems analysis of sterile processing: decontamination. *BMJ Qual Saf* . 2020;29(4):320–328	Organizational Experience	700 bed academic hospital, United States	n/a	n/a	n/a	Effective decontamination requires improved design of instruments and the decontamination area, skilled staff, proper equipment maintenance, and effective coordination of reprocessing tasks.	VA
160	Hoefel HHK, Pozzer C, Acuna A et al. Bundles for the central sterile supply department. *Am J Infect Control.* 2019;47(11):1352–1357	Nonexperimental	Instrument validation using modified Delphi technique, Brazil	n/a	n/a	Bundle elements related to sterile processing	The present study developed an instrument comprising 6 bundles containing items considered essential for process quality and safe use: 2 cleaning bundles, an inspection bundle, a preparation bundle, a sterilization bundle, and a storage and general aspects bundle.	IIIB
161	Mace Davis C, Spear JM. Instrument set decontamination workflows designed for success in sterile processing. *AORN J.* 2021;114(2):149–157	Organizational Experience	Multihospital health system, United States	n/a	n/a	n/a	When there was a pause in elective surgeries in the spring of 2020 as a result of the spread of coronavirus disease 2019, sterile processing personnel became available to participate in a project to create and test these new standardized cleaning pathways and decontamination workflows.	VA