

AORN Guideline for Instrument Care and Cleaning
Evidence Table

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
1	<i>Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff.</i> Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research; March 17, 2015. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling . Accessed August 10, 2020.	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). <i>Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.</i> Atlanta, GA: Centers for Disease Control and Prevention; 2008. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/ . Accessed August 10, 2020.	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. Centers for Disease Control and Prevention guideline for the prevention of surgical site infection, 2017. <i>JAMA Surg.</i> 2017;152(8):784-791	Guideline	n/a	n/a	n/a	n/a	Systematic review including 170 studies with conclusions reached regarding preoperative bathing, antimicrobial prophylaxis, preoperative skin antiseptics, glycemic control, normothermia, blood transfusion, oxygen supplementation, instrument processing, and quality improvement programs.	IVA
4	Jinadatha C, Bridges A. Cleaning, disinfection, and sterilization. In: <i>APIC Text of Infection Control and Epidemiology.</i> Arlington, VA: Association for Professionals in Infection Control and Epidemiology; 2018. http://text.apic.org/toc/basic-principles-of-infection-prevention-practice/cleaning-disinfection-and-sterilization . Accessed August 10, 2020	Position Statement	n/a	n/a	n/a	n/a	All invasive procedures involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. The level of disinfection or sterilization is dependent on the intended use of the object: critical (items that contact sterile tissue such as surgical instruments), semi critical (items that contact mucous membrane such as endoscopes), and noncritical (devices that contact only intact skin such as stethoscopes) items require sterilization, high-level disinfection, and low-level disinfection, respectively. Cleaning (the removal of foreign material) must always precede disinfection and sterilization. In addition, environmental cleaning and disinfection are also essential for maintaining a safe patient environment.	IVA
5	<i>ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.</i> Arlington, VA: 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

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6	Reprocessing of reusable medical devices. US Food and Drug Administration. https://www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-reusable-medical-devices . Accessed August 10, 2020	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	n/a
7	Guideline for sterilization. In: <i>Guidelines for Perioperative Practice</i> . Denver, CO: AORN, Inc; 2020:959-988	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for sterilization practices in the health care organization	IVA
8	Guideline for high-level disinfection. In: <i>Guidelines for Perioperative Practice</i> . Denver, CO: AORN, Inc; 2020:299-326	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 sterilization packaging systems. In: <i>Guidelines for Perioperative Practice</i> . Denver, CO: AORN, Inc; 2020:551-570	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
10	Guideline for processing flexible endoscopes. In: <i>Guidelines for Perioperative Practice</i> . Denver, CO: AORN, Inc; 2020:183-272	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for processing flexible endoscopes	IVA
11	21 CFR 860: Medical Device Classification Procedures. https://www.ecfr.gov/cgi-bin/text-idx?SID=fee96239054dab44b0eab0045392d3b1&mc=true&tpl=/ecfrbrowse/Title21/21cfr860_main_02.tpl . Accessed August 10, 2020	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
12	21 CFR 814: Premarket approval of medical devices. https://www.ecfr.gov/cgi-bin/text-idx?SID=fee96239054dab44b0eab0045392d3b1&mc=true&tpl=/ecfrbrowse/Title21/21cfr814_main_02.tpl . Accessed August 10, 2020.	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
13	21 CFR 807.81-100. Subpart E—Premarket notification procedures. https://www.ecfr.gov/cgi-bin/text-idx?SID=c0bb7f852d0f89888f63a20b427f609a&mc=true&node=sp21.8.807.e&rgn=div6 . Accessed August 10, 2020	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

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14	<i>AAMI TIR12: 2010 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing In Health Care Facilities: A Guide for Medical Device Manufacturers.</i> Arlington, VA: Association for the Advancement of Medical Instrumentation; 2010	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
15	<i>ANSI/AAMI/ISO 17664:2017: Processing of Health Care Products—Information to be Provided by the Medical Device Manufacturer for the Processing of Medical Devices.</i> Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017	Consensus	n/a	n/a	n/a	n/a	International consensus standard that specifies requirements for information to be provided by the medical device manufacturer for the processing of a medical device . This includes information for processing prior to use or reuse of the medical device. Processing instructions are not defined in this standard. Rather, this standard specifies requirements to assist manufacturers of medical devices in providing detailed processing instructions that consist of the following activities where applicable: a) Pre-treatment at the point of use before processing; b) Preparation before cleaning; c) Cleaning; d) Disinfection; e) Drying; f) Inspection, maintenance and functionality testing; g) Packaging; h) Sterilization; i) Storage; j) Transportation.	IVC
16	<i>AAMI TIR30:2011/(R)2016: A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices.</i> Arlington, VA: Association for the Advancement of Medical Instrumentation; 2016	Consensus	n/a	n/a	n/a	n/a	Resource for manufacturers of medical devices who must validate the instructions for reprocessing that they include with their devices. Describes available processes, materials, test methods, and acceptance criteria for cleaning medical devices that are labeled by the manufacturer for reuse and reprocessing, and some of the underlying problems and challenges associated with validating a cleaning method.	IVC
17	<i>ASTM E2314-03(2014): Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test).</i> West Conshohocken, PA: ASTM International; 2014	Consensus	n/a	n/a	n/a	n/a	International consensus standards that describes microbiologic test methods for medical device cleaning validation study.	IVC
18	Guideline for medical device and product evaluation. In: <i>Guidelines for Perioperative Practice.</i> Denver, CO: AORN, Inc; 2020:705-714	Guideline	n/a	n/a	n/a	n/a	Evidence-based practice recommendations for perioperative medical device and product evaluation	IVA
19	<i>AAMI TIR55:2014/(R)2017: Human Factors Engineering for Processing Medical Devices.</i> Arlington, VA: 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

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20	Moss R, Prescott DM, Spear JM. Instrument manufacturing: implications for perioperative teams. <i>AORN J.</i> 2020;112(1):15-29	Expert Opinion	n/a	n/a	n/a	n/a	Perioperative RNs should partner with surgeons, sterile processing department personnel and the manufacturers' representatives to discuss the scope and use and plans for processing as surgical instrument' functionality can affect procedure efficiency, patient outcomes, and surgeon satisfaction.	VB
21	Guideline for design and maintenance of the surgical suite. In: <i>Guidelines for Perioperative Practice.</i> Denver, CO: AORN,	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for providing for optimal surgical suite design and maintenance	IVA
22	Facility Guidelines Institute. <i>Guidelines for Design and Construction of Hospitals.</i> Chicago, IL: American Society for Healthcare Engineering; 2018	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.	IVA
23	Facility Guidelines Institute. <i>Guidelines for Design and Construction of Outpatient Facilities.</i> Chicago, IL: American Society for Healthcare Engineering; 2018	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.	IVA
24	Guideline for a safe environment of care. In: <i>Guidelines for Perioperative Practice.</i> Denver, CO: AORN, Inc; 2020:115-150	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
25	ASCs must work harder to prevent aerosol infectants: human version of mad cow disease is one risk. <i>Same Day Surg.</i> 2018;42(2):13-16	Expert Opinion	n/a	n/a	n/a	n/a	The article features an interview with a Joint Commission surveyor discusses the need for Ambulatory Service Centers (ASCs) to prevent aerosol infectants and cross contamination	VA
26	29 CFR 1910.151: Medical services and first aid. https://www.ecfr.gov/cgi-bin/text-idx?SID=388646509705aeefe60fb39193d0be16&mc=true&node=sp29.5.1910.k&rgn=div6 . Accessed August 10, 2020	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations (law) regarding medical services and first aid	n/a
27	29 CFR 1910.1030: Bloodborne pathogens. https://www.ecfr.gov/cgi-bin/text-idx?SID=72702951fccf826f45871ad7fdb3593f&mc=true&node=se29.6.1910_11030&rgn=div8 . Accessed August 10, 2020	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations (law) regarding bloodborne pathogens	n/a
28	Alfa MJ, Olson N, Al-Fadhaly A. Cleaning efficacy of medical device washers in North American healthcare facilities. <i>J Hosp Infect.</i> 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
29	<i>ASTM D7225-13(2019)e1: Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors.</i> West Conshohocken, PA: 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 using standardized test soils; published by ASTM International.	IVC

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30	Rutala WA, Gergen MF, Weber DJ. Efficacy of a washer-disinfector in eliminating healthcare-associated pathogens from surgical instruments. <i>Infect Control Hosp Epidemiol.</i> 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
31	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. <i>PDA J Pharm Sci Technol.</i> 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	VA
32	AAMI TIR34: 2014/(R)2017: Technical Information Report: Water for the Reprocessing of Medical Devices. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Consensus	n/a	n/a	n/a	n/a	Covers the selection and maintenance of effective water quality suitable for reprocessing medical devices. It provides guidance for selecting the water quality necessary for the reprocessing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations.	IVC
33	Piil JF, Lundbye-Jensen J, Trangmar SJ, Nybo L. Performance in complex motor tasks deteriorates in hyperthermic humans. <i>Temperature (Austin).</i> 2017;4(4):420-428.	Nonexperimental	10 healthy males	n/a	n/a	performance of motor-cognitive testing in different temperature conditions	Simple motor task performance as well as performance in more complex motor tasks may be maintained during passive moderate heat exposure and following moderate elevations in the internal temperature. However, when heat stress result in profound hyperthermia the ability to perform tasks relying on motor accuracy becomes impaired and the effects appears to aggravate if complexity of the motor task increases and further decrements are observed with increasing task conditioning complexity.	IIIB

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34	<i>ASHRAE 188-2018: Legionellosis: Risk Management for Building Water Systems.</i> Atlanta, GA: ASHRAE; 2018	Regulatory	n/a	n/a	n/a	n/a	Establishes minimum legionellosis risk management requirements for building water systems. Included in this publication are a description of environmental conditions that promote the growth of Legionella, and informative annexes and bibliography with suggestions, recommendations, and references to additional guidance. The 2018 revision includes clarification of compliance requirements, as well as a comprehensive update to enforceable, code-intended language. Standard 188 is essential for anyone involved in design, construction, installation, commissioning, operation, maintenance, and service of centralized building water systems and components.	n/a
35	<i>Requirement to Reduce Legionella Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease.</i> Washington, DC: Department of Health and Human Services; 2017. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-And-Cert-Letter-17-30- . Accessed August 10, 2020	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
36	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. <i>Infect Control Hosp Epidemiol.</i>	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
37	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. <i>J Hosp Infect.</i> 2016;93(1):22-28	Organizational Experience	CIO2 treatment in a 1000-bed medical center with two towers and three ICUs.	n/a	n/a	n/a	Addition of a CIO2 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
38	Walker J, Moore G. Safe water in healthcare premises. <i>J Hosp Infect.</i> 2016;94(1):1	Expert Opinion	n/a	n/a	n/a	n/a	Editorial that contrasts published studies focused the relationship between water quality, sink drains, and healthcare acquired infections. Concludes that outbreaks can be related to a number of sources related to water and these sources should be identified in each event to inform improvement efforts.	VA
39	<i>Developing a Water Management Program to Reduce Legionella Growth and Spread in Buildings: A Practical Guide to Implementing Industry Standards.</i> Version 1.1. Washington, DC: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2017	Expert Opinion	n/a	n/a	n/a	n/a	CDC guidance and tool kit for creating a water management program required by CMS	VA

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40	Marek, A., Smith, A., Peat, M., et al. Endoscopy supply water and final rinse testing: five years of experience 2014	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	VA
41	Borella P, Bargellini A, Marchegiano P, Vecchi E, Marchesi I. Hospital-acquired <i>Legionella</i> infections: an update on the procedures for controlling environmental contamination. <i>Ann Ig.</i> 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
42	Casini B, Buzzigoli A, Cristina ML, et al. Long-term effects of hospital water network disinfection on <i>Legionella</i> and other waterborne bacteria in an Italian university hospital. <i>Infect Control Hosp Epidemiol.</i> 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	n/a	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 <i>Legionella pneumophila</i> 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
43	D'Alessandro D, Fabiani M, Cerquetani F, Orsi GB. Trend of <i>Legionella</i> colonization in hospital water supply. <i>Ann Ig.</i> 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 <i>Legionella</i> 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 <i>Legionella</i> 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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44	Demirjian A, Lucas CE, Garrison LE, et al. The importance of clinical surveillance in detecting legionnaires' disease outbreaks: a large outbreak in a hospital with a <i>Legionella</i> disinfection system– Pennsylvania, 2011-2012. <i>Clin Infect Dis.</i> 2015;60(11):1596-1602	Nonexperimental	An outbreak and contributing factors in a single hospital using copper-silver ionization for prevention of <i>Legionella</i> growth in water.	n/a	n/a	Five definite and 17 probable healthcare-associated <i>Legionella</i> cases; 6 case patients died. Of 25 locations (mostly potable water) where environmental samples were obtained for <i>Legionella</i> -specific culture, all but 2 showed <i>Legionella</i> 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 <i>Legionella</i> control. Despite this, all samples where copper and silver concentrations were tested showed <i>Legionella</i>	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
45	Marinelli L, Cottarelli A, Solimini AG, Del Cimmuto A, De Giusti M. Evaluation of timing of re-appearance of VBNC <i>Legionella</i> for risk assessment in hospital water distribution systems. <i>Ann Ig.</i> 2017;29(5):431-439	Nonexperimental	Presence of <i>Legionella</i> species, viable but non-culturable (VBNC), in hospital water networks and the time and load of <i>Legionella</i> 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 <i>Legionella</i> by the standard culture method and were monitored for up to 12 months for the appearance of VBNC <i>Legionella</i> . RESULTS: All the 42 samples were negative at the time of collection. Seven of the 42 samples (17.0%) became positive for <i>Legionella</i> at different times of monitoring. The time to the appearance of VBNC <i>Legionella</i> was extremely variable, from 15 days to 9 months from sampling. The most frequent <i>Legionella</i> species observed were <i>Legionella</i> spp and <i>L. anisa</i> and only in one sample <i>L. pneumophila</i> spp 1	Confirms the presence of VBNC <i>Legionella</i> 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
46	Moore G, Stevenson D, Thompson K, et al. Biofilm formation in an experimental water distribution system: the contamination of non-touch sensor taps and the implication for healthcare. <i>Biofouling.</i> 2015;31(9-10):677-687.	Quasi-experimental	27 tap assemblies	<i>P. aeruginosa</i> 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. <i>P. aeruginosa</i> 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 <i>p. aeruginosa</i>	<i>P. aeruginosa</i> was recovered from all dismantled solenoid valves with colonization of the ethylene propylene diene monomer (EPDM) diaphragm . Removing the solenoid valves reduced <i>P. aeruginosa</i> counts in the water to below detectable levels. This effect was immediate and sustained, implicating the solenoid diaphragm as the primary contamination source for <i>p. aeruginosa</i> .	IIA

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47	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. <i>Indian J Pathol Microbiol</i> . 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 antiseptics 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
48	<i>Decontamination and Reprocessing of Medical Devices for Health-care Facilities</i> . Geneva, Switzerland: World Health Organization and the Pan American Health Organization; 2016.	Guideline	n/a	n/a	n/a	n/a	World Health Organization guideline for decontamination and processing of medical devices	IVB
49	Stiefel P, Mauerhofer S, Schneider J, Maniura-Weber K, Rosenberg U, Ren Q. Enzymes enhance biofilm removal efficiency of cleaners. <i>Antimicrob Agents Chemother</i> . 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 of P. 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
50	Juturu V, Wu JC. Microbial cellulases: engineering, production and applications. <i>Renew Sust Energy Rev</i> . 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
51	<i>Medical Washers and Medical Washer-Disinfectors—Class II Special Controls Guidance for the Medical Device Industry and FDA Review Staff</i> . Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health; 2002. 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 . Accessed	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
52	Crawford M. How clean is clean? Chemistry can damage medical equipment in the quest to meet stringent guidelines. <i>Biomed Instrum Technol</i> . 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

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53	Final Guidance on Environmentally Preferable Purchasing. 1999. US Environmental Protection Agency. https://www.epa.gov/sites/production/files/2015-09/documents/finalepguidance.pdf . Accessed August 11, 2020.	Regulatory	n/a	n/a	n/a	n/a	EPA guidance on environmentally preferable purchasing in the US	n/a
54	EPA's Safer Choice Standard. US Environmental Protection Agency. https://www.epa.gov/sites/production/files/2013-12/documents/standard-for-safer-products.pdf . Revised February 2015. Accessed August 11, 2020	Regulatory	n/a	n/a	n/a	n/a	The U.S. Environmental Protection Agency's (EPA's) Safer Choice Program works in partnership with a broad range of stakeholders to reduce risk to people and the environment by preventing pollution. Safer Choice focuses on industries that combine the potential for chemical risk reduction and improvements in energy efficiency with a strong motivation to make lasting, positive changes.	n/a
55	29 CFR 1910.1200: Toxic and hazardous substances. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1200 . Accessed August 10, 2020.	Regulatory	n/a	n/a	n/a	n/a	Code of Federal Regulations (law) regarding toxic and hazardous substances. OSHA	n/a
56	Basile RJ, Kovach S, Drosnock MA. Guidelines for selecting a cleaning brush. <i>Biomed Instrum Technol.</i> 2019;53(s2):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
57	Rutala WA, Weber DJ. Disinfection and sterilization: an overview. <i>Am J Infect Control.</i> 2013;41(5 Suppl):S2-S5.	Expert Opinion	n/a	n/a	n/a	n/a	When properly used, disinfection and sterilization can provide for the safe use of invasive medical devices; cleaning should always precede high level disinfection and sterilization and strict adherence to current disinfection/sterilization guidance is essential to prevent HAIs and exposure to infectious agents.	VA
58	ANSI/AAMI ST58:2013/(R)2018: <i>Chemical Sterilization and High-Level Disinfection in Health Care Facilities</i> . Arlington, VA: Association for the Advancement of Medical Instrumentation; 2018.	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
59	ANSI/AAMI ST91:2015: <i>Flexible and Semi-Rigid Endoscope Processing in Healthcare Facilities</i> . Arlington, VA: Association for the Advancement of Medical Instrumentation; 2015.	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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60	<i>ANSI/AAMI ST41:2008/(R)2018: Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness</i> . Arlington, VA: Association for the Advancement of Medical Instrumentation; 2018.	Consensus	n/a	n/a	n/a	n/a	Consensus recommendations for safe and effective use of ethylene oxide sterilization in health care.	IVC
61	Class 2 device recall BIOMET Orthopedics. US Food & Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=180539 . February 26, 2020. Accessed August 11, 2020.	Regulatory	n/a	n/a	n/a	n/a	Potentially insufficient cleaning process or potential inadequate process monitoring for cleaning parameters.	n/a
62	Seavey R. High-level disinfection, sterilization, and antisepsis: current issues in reprocessing medical and surgical instruments. <i>Am J Infect Control</i> . 2013;41(5 Suppl):S111-S117.	Expert Opinion	n/a	n/a	n/a	n/a	Current issues that sterile processing and operating room professionals must deal with regarding reprocessing of medical and surgical instruments related to rapid changes in technology. The intricate design of instruments, the configuration of instrument trays, and evidence-based practice have resulted in the need for complicated and specific reprocessing recommendations from instrument manufacturers. Patient safety depends on instruments that are appropriately cared for and adequately reprocessed. This article covers current issues that sterile processing and operating room professionals must deal with regarding reprocessing of medical and surgical	VA
63	Veiga-Malta I. Preventing healthcare-associated infections by monitoring the cleanliness of medical devices and other critical points in a sterilization service. <i>Biomed Instrum Technol</i> . 2016;50(Suppl	Nonexperimental	workers hands, work surfaces, and decontaminated instruments in a central sterile processing department	n/a	n/a	ATP bioluminescence testing for all surfaces and hands	The use of ATP bioluminescence allowed the authors to identify contamination and correct the causes in real-time; evaluation of workers' hands reinforced the importance of hand hygiene in the sterile processing environment	IIIC
64	Costa DM, Lopes LKO, Vickery K, et al. Reprocessing safety issues associated with complex-design orthopaedic loaned surgical instruments and implants. <i>Injury</i> . 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
65	<i>AST Standards of Practice for the Decontamination of Surgical Instruments</i> . Littleton, CO: Association of Surgical Technologists; 2009. https://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Decontamination_%20Surgical_Instruments_.pdf . Accessed August 10, 2020.	Consensus	n/a	n/a	n/a	n/a	AST guideline for the role of the surgical technologist during decontamination of surgical instruments.	IVC

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66	Almatroudi A, Tahir S, Hu H, et al. Staphylococcus aureus dry-surface biofilms are more resistant to heat treatment than traditional hydrated biofilms. <i>J Hosp Infect.</i> 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
67	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. <i>Biofouling.</i> 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
68	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. <i>Am J Infect Control.</i> 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
69	Bezek K, Nipič D, Torkar KG, et al. Biofouling of stainless steel surfaces by four common pathogens: the effects of glucose concentration, temperature and surface roughness. <i>Biofouling.</i> 2019;35(3):273-283.	Quasi-experimental	stainless steel surfaces - untreated, brushed, and electropolished	evaluation of the effects of glucose concentration, temperature, and stainless steel roughness on biofouling by Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa and L. Monocytogenes.	comparison among the variables	extent of biofouling on each surface under different conditions	Among the tested variables, the untreated stainless steel surface was shown to be fouled more than 3D polished, brushed or electropolished surfaces. Although an array of parameters influenced biofouling, the most promising control measure was the influence of low temperature that reduced biofouling even in the case of the psychrophilic Listeria monocytogenes. The study findings could significantly contribute to the prevention of surface contamination and consequential biofouling by food and healthcare associated pathogens.	IIA
70	Lindgren KE, Pelt CE, Anderson MB, Peters CL, Spivak ES, Gililland JM. A chlorhexidine solution reduces aerobic organism growth in operative splash basins in a randomized controlled trial. <i>J Arthroplasty.</i> 2018;33(1):211-215.	RCT	111 splash basins randomized into one of two groups: sterile water (standard of care) or sterile water plus 0.05% CHG	addition of CHG to sterile water used as a "splash basin" during surgical procedures.	standard of care "splash basin" - sterile water only	bacterial growth from a 20mL sample of the splash basin after surgical procedure completion	bacterial growth in 9% of the sterile water compared to no growth in the CHG group (P=0.045). The researchers recommended adding CHG as a control measure to suppress microbial growth in splash basins used intraoperatively.	IB

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71	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. <i>Biomed Instrum Technol</i> . 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
72	Guideline for sharps safety. In: <i>Guidelines for Perioperative Practice</i> . Denver, CO: AORN, Inc; 2020:859-882.	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for perioperative sharps safety	IVA
73	Guideline for transmission-based precautions. In: <i>Guidelines for Perioperative Practice</i> . Denver, CO: AORN, Inc; 2020:1071-	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for perioperative transmission-based precautions	IVA
74	Almatroudi A, Hu H, Deva A, et al. A new dry-surface biofilm model: an essential tool for efficacy testing of hospital surface decontamination procedures. <i>J Microbiol Methods</i> . 2015;117:171-176.	Quasi-experimental	24 removable, sterile polycarbonate coupons in an intensely cleaned, brushed and steam sterilized CDC biofilm reactor to grow a semi-dehydrated model biofilm	after comparison to clinical biofilm, the model biofilm was fixed with 3% glutaraldehyde followed by dehydration with ethanol.	clinical biofilm	creation of a model biofilm	The researchers produced a model biofilm which has similar characteristics when compared to clinical biofilms and propose that this study's method is suitable for efficacy testing of decontamination products against biofilms.	IIA
75	Guideline for sterile technique. In: <i>Guidelines for Perioperative Practice</i> . Denver, CO: AORN, Inc; 2020:917-958.	Guideline	n/a	n/a	n/a	n/a	Evidence-based practice recommendations for sterile technique in the perioperative setting	IVA
76	<i>ASTM F1744-96(2016): Standard Guide for Care and Handling of Stainless Steel Surgical Instruments</i> . West Conshohocken, PA: ASTM International; 2016.	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
77	Spruce L. Back to basics: instrument cleaning. <i>AORN J</i> . 2017;105(3):292-299.	Expert Opinion	n/a	n/a	n/a	n/a	Adequately cleaning and processing surgical instruments may be challenging for perioperative team members; however, the cleaning and processing of instruments are critical steps in making instruments safe to use on patients and achieving an appropriately safe OR environment. Instruments that are cleaned properly have had organic debris and soil removed, rendering them ready for sterilization or disinfection. This Back to Basics article covers the basic steps and considerations for cleaning and processing instruments before sterilization.	VA
78	Baruque Villar G, de Mello Freitas FT, Pais Ramos J, et al. Risk factors for Mycobacterium abscessus subsp. bolletii infection after laparoscopic surgery during an outbreak in Brazil. <i>Infect Control Hosp Epidemiol</i> . 2015;36(1):81-86.	Nonexperimental	222 patients who had undergone laparoscopic surgery in a single institution in Manaus, Brazil	n/a	n/a	surgical site infection	60 (27%) cases of infection. After multivariate analysis, the duration of surgery beyond 1 hour (odds ratio [OR] 2.4; 95% confidence interval [CI] 1.2-4.5), not to have been the first operated patient on a given day (OR, 2.7; 95% CI, 1.4-5.2), and the use of permanent trocar (OR, 2.2; 95% CI, 1.1-4.2) were associated with infection. We observed that the surgical team attempted to sterilize the equipment in glutaraldehyde solution when sanitary authorities had already prohibited it. Eleven strains presented 100% DNA identity with a single strain, known as BRA100 clone. Effective processing of video-assisted surgery equipment was crucial to stopping this single clonal outbreak of nontuberculous mycobacteria in Brazil.	IIIC

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79	Weber DJ, Rutala WA. Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. <i>Am J Infect Control.</i> 2013;41(5 Suppl):S67-S71.	Expert Opinion	n/a	n/a	n/a	n/a	. Failure to ensure proper cleaning and sterilization or disinfection may lead to patient-to-patient transmission of pathogens. This paper describes a protocol that can guide an institution in managing potential disinfection and sterilization failures.; Medical devices that enter body tissues should be sterile, whereas devices that contact mucous membranes should be high-level disinfected between patients. Failure to ensure proper cleaning and sterilization or disinfection may lead to patient-to-patient transmission of pathogens. This paper describes a protocol that can guide an institution in managing potential disinfection and sterilization	VA
80	Roth V, Espino-Grosso P, Henriksen C, Canales B. Cost and UTI rate following office cystoscopy before and after implementing new standardized handling and storage practices. <i>J Urol.</i> 2019;201(Suppl 4):e1137.	Organizational Experience	1,888 veterans	n/a	n/a	n/a	Urinary tract infection rates were similar among patients whose cystoscopy procedure was performed with cystoscopes were processed in different ways; prophylactic antibiotics were prescribed in both cohorts	VA
81	Bilavsky E, Pfeffer I, Tarabeia J, et al. Outbreak of multidrug-resistant <i>Pseudomonas aeruginosa</i> infection following urodynamic studies traced to contaminated transducer. <i>J Hosp Infect.</i> 2013;83(4):344-346.	Case Report	n/a	n/a	n/a	n/a	nosocomial outbreak of urinary tract infection by extremely drug resistant <i>Pseudomonas aeruginosa</i> , susceptible only to colistin. Infection in three patients followed urodynamic studies. Two of the three patients were children, one of whom also developed urosepsis. The investigation led to detection of contaminated pressure transducers. Genotyping confirmed that patient and transducer isolates were identical. These transducers were not labelled as 'single use only' despite the possibility that contaminated urine may reflux and mix with the fluid in the device. The issue of re-usable versus single-use urodynamic devices is	VA
82	Scorzolini L, Mengoni F, Mastroianni CM, et al. Pseudo-outbreak of <i>Mycobacterium gordonae</i> in a teaching hospital: importance of strictly following decontamination procedures and emerging issues concerning sterilization. <i>New Microbiol.</i> 2016;39(1):25-34.	Case Report	n/a	n/a	n/a	n/a	<i>Mycobacterium gordonae</i> was detected in 7 out of 497 broncho-alveolar lavage (BAL) samples after bronchoscopy procedure in patients admitted to a teaching hospital between January and April 2013. During this pseudo-outbreak clinical, epidemiological, environmental and molecular investigations were performed. None of the patients met the criteria for non-tuberculous mycobacterial (NTM) lung disease and were treated for <i>M. gordonae</i> lung disease. Environmental investigation revealed <i>M. gordonae</i> in 3 samples: in tap water and in the water supply channel of the washer disinfectant. All the isolates were subjected to genotyping by pulsed-field gel electrophoresis (PFGE). The PFGE revealed that only patients' isolates presented the same band pattern but no correlation with the environmental strain was detected. Surveillance of the outbreak and the strict adherence to the reprocessing procedure and its supplies resulted afterwards in no detection of <i>M. gordonae</i> in clinical respiratory samples. Clinical surveillance of patients was crucial to establish the start of NTM treatment. Regular screening of tap water and endoscopic equipment should be adopted to compare the clinical strains with the environmental ones when an outbreak occurs.	VA

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83	Dupont C, Terru D, Aguilhon S, et al. Source-case investigation of Mycobacterium wolinskyi cardiac surgical site infection. <i>J Hosp Infect.</i> 2016;93(3):235-239.	Organizational Experience		n/a	n/a	n/a	The non-tuberculous mycobacteria (NTM) Mycobacterium wolinskyi caused bacteremia and massive colonization of an aortic prosthesis in a patient 16 days after cardiac surgery, necessitating repeat surgery and targeted antimicrobial chemotherapy. The infection control team investigated the source and conditions of infection. Peri-operative management of the patient complied with recommendations. The environmental investigation showed that although M. wolinskyi was not recovered, diverse NTM species were present in water from point-of-use taps and heater-cooler units for extracorporeal circulation. This case and increasing evidence of emerging NTM infections in cardiac surgery led to the implementation of infection control procedures in cardiac surgery wards.	VA
84	Kumarage J, Khonyongwa K, Khan A, Desai N, Hoffman P, Taori SK. Transmission of multi-drug resistant Pseudomonas aeruginosa between two flexible ureteroscopes and an outbreak of urinary tract infection: the fragility of endoscope decontamination. <i>J Hosp Infect.</i> 2019;102(1):89-94.	Case Report	n/a	n/a	n/a	n/a	Thirteen patients developed clinical infections linked to two flexible ureteroscopes. The first ureteroscope was likely colonized from a known infected patient and the second ureteroscope after use on another patient infected by the first. Risk factors identified include surface cuts, stretching and puckering of the outer cover in both ureteroscopes, absence of bedside cleaning, overnight delay between the ureteroscopy and decontamination, inadequate drying after decontamination and non-traceability of connector valves. The adequacy of flexible endoscope decontamination depends on numerous steps. With the increasing global incidence of multi-drug resistant organisms, stringent monitoring of the flexible endoscopy process by users and decontamination units is essential.	VA
85	Guideline for environmental cleaning. In: <i>Guidelines for Perioperative Practice</i> . Denver, CO: AORN, Inc; 2020:151-182.	Guideline	n/a	n/a	n/a	n/a	Evidence-based guideline providing recommendations for environmental cleaning of the perioperative area	IVA
86	Stjärne Aspelund A, Sjöström K, Olsson Liljequist B, Mörgelin M, Melander E, Pålman LI. Acetic acid as a decontamination method for sink drains in a nosocomial outbreak of metallo-β-lactamase-producing Pseudomonas aeruginosa. <i>J Hosp Infect.</i> 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

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87	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. <i>J Hosp Infect.</i> 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
88	Alfa MJ, Olson N. Comparison of washer-disinfector cleaning indicators: impact of temperature and cleaning cycle parameters. <i>Am J Infect Control.</i> 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,	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
89	Czyrko C. Effective infection control procedures: ultrasonic cleaners. <i>Dent Nurs.</i> 2015;11(8):469-471.	Expert Opinion	n/a	n/a	n/a	n/a	The article discusses ultrasonic cleaners as the most efficient method for cleaning and decontaminating reusable dental equipment. Topics covered include the ever-increasing focus on the importance of infection prevention and control, how infection control procedures should protect dental staff and patients, and the pre-sterilization cleaning with ultrasonic	VC
90	Di Blasio A, Barengi L. Pitfalls of cleaning controls in ultrasonic washers. <i>Am J Infect Control.</i> 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 main means of cleaning efficacy; strict guidelines and well-designed protocols and clear IFUs, and appropriate solutions and test soils are needed for correct ultrasonic washer use.	VA
91	Kean R, Johnson R, Doyle M. Code grey: stained surgical instruments and their impact on one Canadian health authority. <i>Healthc Q.</i> 2017;20(3):65-68.	Organizational Experience	two hospitals in one health system	n/a	n/a	n/a	Stained surgical instruments at its two largest hospitals. This discovery prompted a series of postponed surgeries, an extensive internal mobilization of labor and the purchase of millions of dollars of new equipment. In tackling these challenges, the organization not only acquired a better understanding of its surgical tools, but it also gained renewed appreciation for the resilience of its human resources. By describing this incident and the lessons learned, we hope to offer insight to providers in similar	VA

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REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
92	Moi LL, Joo TL, Meh MG. Cleaning verification in medical device reprocessing: is this required? <i>Can J Infect Control</i> . 2015;30(4):237-238.	Quasi-experimental	240 surgical instruments (rongeur, long forceps, powered tools and hollow suction tubes) in a 1,750-bed Singapore General Hospital	soaking with multi-enzyme concentrate for 5 minutes followed by washing in an automatic washer-disinfector except powered tools which were manually washed	Pre- and Post- cleaning ATP levels using an ATP luminator	visual inspection and ATP testing	cleaning validation is best done with visual inspection combined with ATP test, as these methods assess cleanliness of both external surfaces and inner channels of medical devices.	IIB
93	Huang Y, Chen Y, Chen M, et al. Comparing visual inspection, aerobic colony counts, and adenosine triphosphate bioluminescence assay for evaluating surface cleanliness at a medical center. <i>Am J Infect Control</i> . 2015;43(8):882-886.	Organizational Experience	10 surfaces evaluated with visual inspection, aerobic colony counts, and adenosine triphosphate bioluminescence assay	n/a	n/a	n/a	ATP assay had better sensitivity than visual inspection (63.6% vs 27.3%) to evaluate cleanliness	VB
94	Schmitt C, Pires Maciel AL, Boszczowski I, et al. Evaluation of adenosine triphosphate test for cleaning assessment of gastroscopes and the effect on workload in a busy endoscopy center. <i>Am J Infect Control</i> . 2018;46(10):1110-1114.	Nonexperimental	24 samples collected from 10 gastroscopes	n/a	n/a	ATP bioluminescence testing, bioburden presence, residual protein	ATP tests for gastroscope cleaning monitoring are easy to perform and provide immediate feedback to personnel. However, further studies regarding the optimal cutoff for ATP testing of manual cleaning are needed. The decision to add ATP tests into the routine of endoscopy centers should consider the increase in workload.	IIIA
95	Alfa MJ. Monitoring and improving the effectiveness of cleaning medical and surgical devices. <i>Am J Infect Control</i> . 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 reproducible 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
95	Alfa MJ. Monitoring and improving the effectiveness of cleaning medical and surgical devices. <i>Am J Infect Control</i> . 2013;41(5 Suppl):S56-S59.	Expert Opinion	n/a	n/a	n/a	n/a	The author stresses the importance of monitoring of manual and automated cleaning to have a more objective measure of clean prior to advancing a medical device to the next level of processing including disinfection and sterilization.	VA
96	Saito Y, Yasuhara H, Murakoshi S, Komatsu T, Fukatsu K, Uetera Y. Novel concept of cleanliness of instruments for robotic surgery. <i>J Hosp Infect</i> . 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
97	Gillespie E, Othman N, Irwin L. Using ultraviolet visible markers in sterilizing departments. <i>Am J Infect Control</i> . 2014;42(12):1343.	Expert Opinion	n/a	n/a	n/a	n/a	Using ultraviolet markers provides an objective monitoring tool to assess environmental cleaning and is easily adaptable to established process improvement systems.	VB
98	Saito Y, Yasuhara H, Murakoshi S, Komatsu T, Fukatsu K, Uetera Y. Challenging residual contamination of instruments for robotic surgery in Japan. <i>Infect Control Hosp Epidemiol</i> . 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

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99	Kurley B. ATP testing: an anecdotal look at its use in an office-based plastic surgery setting. <i>Plast Surg Nurs.</i> 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
100	<i>Important Information for Infection Preventionists Regarding Media Attention on an Outbreak Involving Reusable Surgical Instruments.</i> Washington, DC: Association for Professionals in Infection Control and Epidemiology (APIC); 2012.	Expert Opinion	n/a	n/a	n/a	n/a	The CPI report is critical of the device manufacturing industry, as well as the FDA, and cites improper cleaning and sterilization related to poor manufacturer design, proliferation of highly complex surgical instruments, and inadequate device testing by manufacturers. The report also cites inadequate pay and stressful working conditions in healthcare settings for sterile processing technicians who are charged with cleaning and sterilizing instruments used in surgical procedures. According to the report, only the state of New Jersey requires professional certification for sterile processing employees.	VA
101	Tosh PK, Disbot M, Duffy JM et al. Outbreak of Pseudomonas aeruginosa surgical site infections after arthroscopic procedures: Texas, 2009. <i>Infect Control Hosp Epidemiol.</i> 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
102	Guideline for electrosurgical safety. In: <i>Guidelines for Perioperative Practice.</i> Denver, CO: AORN, Inc; 2020.	Guideline	n/a	n/a	n/a	n/a	Provides evidence-based recommendations for electrosurgical safety in the operating room.	IVA
103	Chang DF, Mamalis N; Ophthalmic Instrument Cleaning and Sterilization Task Force. Guidelines for the cleaning and sterilization of intraocular surgical instruments. <i>J Cataract Refract Surg.</i> 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
104	Mamalis N. Toxic anterior segment syndrome: role of enzymatic detergents used in the cleaning of intraocular surgical instruments. <i>J Cataract Refract Surg.</i> 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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105	Shorstein NH, Lucido C, Carolan J, Liu L, Slean G, Herrinton LJ. Failure modes and effects analysis of bilateral same-day cataract surgery. <i>J Cataract Refractive Surg.</i> 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
106	Mamalis N, Edelhauser HF. Enzymatic detergents and toxic anterior segment syndrome. <i>Ophthalmology.</i> 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	VA
107	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. <i>J Cataract Refract Surg.</i> 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
108	Valdez-García JE, Climent A, Chávez-Mondragón E, Lozano-Ramírez JF. Anterior chamber bacterial contamination in cataract surgery. <i>BMC Ophthalmol.</i> 2014;14:57. doi: 10.1186/1471-2415-14-57.	Nonexperimental	64 cataract surgeries amount 32 patients	n/a	n/a	bacterial growth in postoperative aspirates	Common contaminating microorganisms included the <i>Staphylococcus</i> species, which was isolated from the eyelids and ocular annexes at the time of wound closure. The isolation of microorganisms postoperatively could have been influenced by the surgical technique used, the surgical time, and the use	IIIA
109	Junk AK, Chen PP, Lin SC, et al. Disinfection of tonometers: a report by the American Academy of Ophthalmology. <i>Ophthalmology.</i> 2017;124(12):1867-1875.	Literature Review	n/a	n/a	n/a	n/a	Literature search - initially yielded 64 unique citations. After exclusion criteria were applied, 10 laboratory studies remained for this review. Nine of the 10 studies used tonometer prisms and 1 used steel discs. The infectious agents covered in this assessment include adenovirus 8 and 19, herpes simplex virus (HSV) 1 and 2, human immunodeficiency virus 1, hepatitis C virus, enterovirus 70, and variant Creutzfeldt-Jakob disease. All 4 studies of adenovirus 8 concluded that after sodium hypochlorite (dilute bleach) disinfection, the virus was undetectable, but only 2 of the 4 studies found that 70% isopropyl alcohol (e.g., alcohol wipes or soaks) eradicated all viable virus. All 3 HSV studies concluded that both sodium hypochlorite and 70% isopropyl alcohol eliminated HSV. Ethanol, 70% isopropyl alcohol, dilute bleach, and mechanical cleaning all lack the ability to remove cellular debris completely, which is necessary to prevent prion transmission. Therefore, single-use tonometer tips or disposable tonometer covers should be considered when treating patients with suspected prion disease. Damage to tonometer prisms can be caused by sodium hypochlorite, 70% isopropyl alcohol, 3% hydrogen peroxide, ethyl alcohol, water immersion, ultraviolet light, and heat exposure. Disinfectants can cause tonometer tips to swell and crack by dissolving the glue that holds the hollow tip together. The tonometer tip cracks can irritate the cornea, harbor microbes, or allow disinfectants to enter the interior of the tonometer tip. Sodium hypochlorite (dilute bleach) offers effective disinfection against adenovirus and HSV, the viruses commonly associated with nosocomial outbreaks in eye care. Tonometer prisms should be examined regularly for	VB

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110	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. <i>J Cataract Refract Surg.</i> 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
111	Choi JH, Cho YS, Lee JW, Shin HB, Lee IK. Bacterial contamination and disinfection status of laryngoscopes stored in emergency crash carts. <i>J Prev Med Pub Health.</i> 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
112	Negri de Sousa AC, Levy CE, Freitas MI. Laryngoscope blades and handles as sources of cross-infection: an integrative review. <i>J Hosp Infect.</i> 2013;83(4):269-275.	Systematic 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.	IIIA
113	Howell, V.; Thoppil, A.; Young, H.; Sharma, S.; Blunt, M.; Young, P. Chlorhexidine to maintain cleanliness of laryngoscope handles. <i>Eur J Anaesthesiol</i> , 2013, 30(5):216-221.	Quasi-experimental	Twenty Heine laryngoscope handles at one hospital in the UK.	Twenty laryngoscope handles were contaminated with microbial broth and then disinfected with chemical wipes, either using Sani-Cloth CHG 2% (chlorhexidine 2%/alcohol 70%) or Tuffie 5 wipes. This was repeated with an interval of 24 h between cleaning and contamination. A further experiment repeatedly re-contaminated the handles at varying time intervals after cleaning. The audit established the current level of contamination of laryngoscope handles within the hospital, and this was repeated following a change in cleaning		Bacterial growth on agar plates was counted as the number of colony forming units.	Decontamination with Sani-Cloth CHG 2% wipes confers additional advantages over routine autoclaving or handle disposal, due to a residual effect. Autoclaving handles may be desirable on a scheduled basis and if <i>Clostridium difficile</i> is encountered.	IIA
114	Sherman, J.; Raibley, L.; Eckelman, M. Life cycle assessment and costing methods for device procurement: Comparing reusable and single-use disposable laryngoscopes. <i>Anesth Analg</i> , 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	IIIA

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115	Van Wicklin SA. Contamination and disinfection of rigid laryngoscopes: a literature review. <i>AORN J.</i> 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	VA
116	Nielsen SW, Stevens JR, Stevens GJ, Patel J, Eller RL. Mandated wrapping of airway cart instruments: limited access without the intended safety benefits. <i>Laryngoscope.</i> 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
117	Rutala WA, Weber DJ; Society for Healthcare Epidemiology of America. Guideline for disinfection and sterilization of prion-contaminated medical instruments. <i>Infect Control Hosp Epidemiol.</i> 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
118	Infection control: iatrogenic transmission of CJD. Centers for Disease Control and Prevention. https://www.cdc.gov/prions/cjd/infection-control.html . Accessed August 11, 2020.	Expert Opinion	n/a	n/a	n/a	n/a	Inactivation studies have not rigorously evaluated the effectiveness of actual cleaning and reprocessing methods used in health care facilities. Recommendations to reprocess instruments potentially contaminated with the CJD agent are primarily derived from in vitro inactivation studies that used either brain tissues or tissue homogenates, both of which pose enormous challenges to any sterilization process.	VA
119	<i>WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies: Report of a WHO Consultation, Geneva, Switzerland, 23-26 March 1999.</i> World Health Organization. https://www.who.int/csr/resources/publications/bse/WHO_CDS_CSR_APH_2000_3/en/ . Accessed August 11, 2020.	Guideline	n/a	n/a	n/a	n/a	World Health Organization guidelines for prevention of transmissible spongiform encephalopathies including CJD	IVA
120	<i>WHO Tables on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies.</i> Geneva, Switzerland: WHO Press; 2010. https://www.who.int/bloodproducts/tablestissueinfectivity.pdf?ua=1s . Accessed August 11, 2020.	Guideline	n/a	n/a	n/a	n/a	World Health Organization infectivity tables: transmissible spongiform encephalopathies	IVA

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121	Thomas JG, Chenoweth CE, Sullivan SE. Iatrogenic Creutzfeldt-Jakob disease via surgical instruments. <i>J Clin Neurosci.</i> 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
122	<i>Patient Safety and Reduction of Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) via Interventional Procedures.</i> London, UK: National Institute for Health and Care Excellence; 2006.	Guideline	n/a	n/a	n/a	n/a	NICE guideline for reduction of procedural (surgical) CJD transmission risk	IVA
123	Fichet G, Antloga K, Comoy E, Deslys JP, McDonnell G. Prion inactivation using a new gaseous hydrogen peroxide sterilisation process. <i>J Hosp Infect.</i> 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
124	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. <i>Infect Control Hosp Epidemiol.</i> 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
125	Rogez-Kreuz C, Yousfi R, Soufflet C, et al. Inactivation of animal and human prions by hydrogen peroxide gas plasma sterilization. <i>Infect Control Hosp Epidemiol.</i> 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
126	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. <i>J Hosp Infect.</i> 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.	IIA

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127	Smith A, Winter S, Lappin D, et al. Reducing the risk of iatrogenic Creutzfeldt-Jakob disease by improving the cleaning of neurosurgical instruments. <i>J Hosp Infect.</i> 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	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
128	Record of decision by principal deputy AA/OPPTS regarding status of prions under FIFRA. US Environmental Protection Agency. https://www.epa.gov/sites/production/files/2015-09/documents/records_of_decision_on_prions.pdf . April 29, 2004. Accessed August 11, 2020.	Regulatory	n/a	n/a	n/a	n/a	This declaration details the decision to classify prions as "pest" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) including a summary of the decision, background on prions, and rationale.	n/a
129	<i>Product Performance Test Guidelines. OCSPP 810.2700: Products with Prion-Related Claims.</i> US National Service Center for Environmental Publications (NSCEP). Environmental Protection Agency. https://nepis.epa.gov/Exe/ZyPDF.cgi/P100IJB7.PDF?Dockkey=P100IJB7.PDF . December 2012. Accessed August 11, 2020.	Regulatory	n/a	n/a	n/a	n/a	Federal guideline that describes test methods that EPA believes will generally satisfy certain testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act for products with prion-related claims.	n/a
130	Search for registered pesticide products. US Environmental Protection Agency. https://www.epa.gov/safepestcontrol/search-registered-pesticide-products . Updated June 19, 2017. Accessed August 11, 2020.	Regulatory	n/a	n/a	n/a	n/a	EPA registered pesticide search website	n/a
131	McDonnell G, Dehen C, Perrin A, et al. Cleaning, disinfection and sterilization of surface prion contamination. <i>J Hosp Infect.</i> 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

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132	Fichet G, Comoy E, Duval C, et al. Novel methods for disinfection of prion-contaminated medical devices. <i>Lancet</i> . 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
133	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. <i>PLoS One</i> . 2016;11(1):e0146833. doi:10.1371/journal.pone.0146833.	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
134	Botsios S, Tittman S, Manuelidis L. Rapid chemical decontamination of infectious CJD and scrapie particles parallels treatments known to disrupt microbes and biofilms. <i>Virulence</i> . 2015;6(8):787-801.	Quasi-experimental	36 inoculated monotypic neuronal GT1 cells	treatment with thio-urea or urea, alone and in combination with β-ME; sonication	no treatment	FU-CJD or 22L scrapie infectivity reduction	A protocol using sonication with these chemical treatments may effectively decontaminate complicated instruments, such as duodenoscopes that harbor additional virulent microbes and biofilms associated with recent iatrogenic infections	IIA
135	Schmitt A, Westner IM, Reznicek L, Michels W, Mitteregger G, Kretzchmar HA. Automated decontamination of surface-adherent prions. <i>J Hosp Infect</i> . 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	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 prion effective compared with standard alkaline cleaning.	IIA
136	Smyth EG, Farrell M, Healy DG, et al. Managing the consequences of neurosurgical intervention in a patient with previously undiagnosed Creutzfeldt-Jakob disease. <i>Infect Control Hosp Epidemiol</i> . 2014;35(7):907-908.	Nonexperimental	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.	IIIA

AORN Guideline for Instrument Care and Cleaning
Evidence Table

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139	Brown P, Farrell M. A practical approach to avoiding iatrogenic Creutzfeldt-Jakob disease (CJD) from invasive instruments. <i>Infect Control Hosp Epidemiol.</i> 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
140	Standards of perioperative nursing practice. AORN, Inc. https://www.aorn.org/guidelines/clinical-resources/aorn-standards . Revised 2009. Accessed August 10, 2020.	Position Statement	n/a	n/a	n/a	n/a	The standards of perioperative nursing provide a mechanism to delineate the responsibilities of RNs engaged in practice in the perioperative setting. These standards serve as the basis for quality monitoring and evaluation systems; databases; regulatory systems; the development and evaluation of nursing service delivery systems and organizational structures; certification activities; job descriptions and performance appraisals; agency policies, procedures, and protocols; and educational offerings.	IVB
141	Duro M. Improving device reprocessing through education and audits. <i>AORN J.</i> 2016;103(1):P13-P14.	Expert Opinion	n/a	n/a	n/a	n/a	Article focused on implementing quality assurance measures including a focus on education and auditing essentials in the sterile processing area.	VA
142	<i>State Operations Manual Appendix A: Survey Protocol, Regulations and Interpretive Guidelines for Hospitals</i> . Rev. 200, 02-21-20. Centers for Medicare & Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf . Accessed August 11, 2020.	Regulatory	n/a	n/a	n/a	n/a	Hospital Medicare Conditions of Participation - manual provides details of compliance requirements. Certification of hospital compliance with the CoP is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a hospital's performance of patient-focused and organizational functions an processes.	n/a
143	<i>State Operations Manual Appendix L: Guidance for Surveyors: Ambulatory Surgical Centers</i> . Rev. 200, 02-21-20. Centers for Medicare & Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf . Accessed August 11, 2020.	Regulatory	n/a	n/a	n/a	n/a	Ambulatory Surgical Centers - Medicare Conditions of Participation - manual provides details of compliance requirements. Certification of hospital compliance with the CoP is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a hospital's performance of patient-focused and organizational functions an processes.	n/a
144	<i>ANSI/AAMI ST90:2017: Processing of Health Care Products: Quality Management Systems for Processing in Health Care Facilities</i> . Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Consensus	n/a	n/a	n/a	n/a	Consensus statement providing recommendations for quality management systems in health care facilities in the US.	IVC

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145	Smith K, Araoye I, Gilbert S, et al. Is retained bone debris in cannulated orthopedic instruments sterile after autoclaving? <i>Am J Infect Control.</i> 2018;46(9):1009-1013.	Quasi-experimental	15 cannulated drill bits	steam sterilization after drilling pig scapulae to create a bone plug that was then exposed to <i>Bacillus cereus</i> , <i>Pseudomonas aeruginosa</i> , and methicillin-resistant <i>Staphylococcus aureus</i> for 60, 120, or 180 minutes prior to sterilization	comparison among the three groups (60, 120, 180 minutes)	culture positivity after steam sterilization cycle	All 3 positive controls were positive for the experimental bacteria. Two negative controls were positive for contaminant bacteria. A <i>B. cereus</i> strain was recovered from 1 of the experimental group drill bits in the 180-minute group. Pulsed-field gel electrophoresis confirmed that the recovered <i>B. cereus</i> strain was identical to the experimental inoculate. Retained biodebris in cannulated drills may not be sterile after standard autoclave sterilization. In addition, delay of surgical instrument reprocessing may increase the risk of resistant contamination	IIB
146	Davis J. Retained bioburden on surgical instruments after reprocessing: are we just scraping the surface? <i>Pennsylvania Patient Safety Advisory.</i> 2017;14(2):71-75.	Expert Opinion	n/a	n/a	n/a	n/a	The design of medical devices, equipment and instruments can provide ideal spaces for bioburden accumulation and subsequent development of surface biofilms especially if compound hinges, haps, channels, or lumens are present. Efforts should be considered to improve departments and processes around the care and maintenance of mission critical instruments devices and equipment	VA
147	Boyle MA, O'Donnell MJ, Russell RJ, Galvin N, Swan J, Coleman DC. Overcoming the problem of residual microbial contamination in dental suction units left by conventional disinfection using novel single component suction handpieces in combination with automated flood disinfection. <i>J Dent.</i> 2015;43(10):1268-1279.	Nonexperimental	25 dental chair unit suction systems including component handpieces	n/a	n/a	microbial growth after processing	Disassembly of components improves disinfection efficacy and considerably reduces cross-contamination risks	IIIC
148	Southworth PM. Infections and exposures: reported incidents associated with unsuccessful decontamination of reusable surgical instruments. <i>J Hosp Infect.</i> 2014;88(3):127-131.	Literature Review	n/a	n/a	n/a	n/a	Articles detailing incidents associated with unsuccessful decontamination of surgical instruments were identified. Twenty-one articles were identified reporting incidents associated with failures in decontamination. A large proportion of incidents involved the attempted disinfection, rather than sterilization, of surgical instruments (43% of articles), counter to a number of national guidelines. Instruments used in eye surgery were most frequently reported to be associated with decontamination failures (29% of articles). Of the few articles detailing potential or confirmed pathogenic transmission, <i>Pseudomonas aeruginosa</i> and <i>Mycobacterium</i> spp. were most represented. One incident of possible variant Creutzfeldt-Jakob disease transmission was also identified. Limitations of analyzing only published incidents mean that the likelihood of under-reporting (including reluctance to publish failure) must be considered. Despite these limitations, the small number of articles identified suggests a relatively low risk of cross-infection through reusable surgical instruments when cleaning/sterilization procedures are adhered to. The diverse nature of reported incidents also suggests that failures are	VA