

## Supplementary Material

# SHEA Expert Guidance: Multisociety Guidance for Sterilization and High-level Disinfection

### Contents

Table 1. Summary of recommendations .....	2
Table 2. Terminology and definitions .....	9
Table 3. Scope.....	10
Table 4. Literature review criteria, search strategies, and PRISMA .....	11
Table 5. Methods for sterilization and high-level disinfection of reusable medical devices.....	17
Table 6. Physical, chemical, and biological indicators.....	18
Table 7. Causes of failure in sterilization and HLD, suggested interventions, and best practices...	20
Table 8. Future Considerations .....	22
References.....	23

# Table 1. Summary of recommendations

#	Question	Recommendation
<b>Prior to sterilization or HLD</b>		
<i>Point-of-use treatment</i>		
1	What is the optimal timing and location for point-of-use treatment?	<ol style="list-style-type: none"> <li>1. Apply point-of-use treatment promptly to initiate the cleaning process and/or to prevent soils from drying on the reusable medical device.</li> <li>2. Perform point-of-use treatment in accordance with the MIFUs for the cleaning product and the medical device.</li> </ol>
2	What are the most effective means of treating a reusable medical device prior to transport to the location where sterilization or HLD will be performed?	<ol style="list-style-type: none"> <li>1. Treat reusable medical devices at the point-of-use with a process designed to begin cleaning and/or to keep devices moist until processing begins.</li> <li>2. Select the product and/or process for point-of-use treatment following the device's MIFU for compatibility and consideration for effectiveness and for limiting adverse interactions with common contaminants (e.g., blood, silicone). Do not use products known to be fixatives (e.g., alcohol) for point-of-use treatment.</li> <li>3. In settings where there is a prolonged interval between the use of the medical device and initiation of processing, and in scenarios where reusable medical devices otherwise would dry out, use moisture retention products that are compatible with the devices, following the device's MIFU and seeking technical data if needed.</li> </ol>
3	What is the recommended response to delays in the start of point-of-use treatment?	<ol style="list-style-type: none"> <li>1. If a delay occurs, follow the MIFU for remediation due to potential for biofilm formation and drying of soils. In the absence of guidance in the MIFU, follow the process described in <i>Section 2. Manufacturers' instructions for use</i>.</li> <li>2. Keep reusable medical devices moist between use and the start of treatment to prevent soils from drying, unless prohibited by the MIFU.</li> </ol>
4	What modifications in point-of-use treatment are required for lumened devices?	<ol style="list-style-type: none"> <li>1. Adhere to the MIFU for each specific lumened device, including instructions for use of the flushing solutions and the appropriate types and sizes of cleaning brushes.</li> <li>2. Never attempt to modify or adapt cleaning instructions intended for non-lumened devices for use on lumened devices.</li> </ol>
5	What are the requirements for transporting contaminated critical or semi-critical devices within the facility to the location of processing?	<ol style="list-style-type: none"> <li>1. Package or contain the reusable medical devices in accordance with Occupational Safety and Health Administration (OSHA) requirements.<sup>1</sup></li> <li>2. Transport contaminated critical or semi-critical devices to the location of processing in a manner that keeps reusable medical devices' surfaces moist, unless prohibited by the MIFU, and prevents damage to the devices, exposure of individuals to body fluids, and contamination of the environment.</li> <li>3. Use a closed, rigid container or closable, fluid-resistant bag to transport contaminated devices.</li> </ol>
6	What packaging-specific issues are relevant for transport outside of the facility to the location of processing?	<ol style="list-style-type: none"> <li>1. Apply the same principles to transport outside of the facility as transport inside the facility in a manner that keeps the reusable medical device's surface moist, unless prohibited by the MIFU, and prevents damage to the medical device or packaging, exposure of individuals to body fluids, and contamination of the environment.</li> <li>2. Consider the effects of exposure to temperature extremes and the potential for damage to the reusable medical devices due to shock and vibration during transport outside of the facility.</li> <li>3. Follow applicable state and federal regulatory requirements related to transport.</li> </ol>
<i>Preparation at the location of processing</i>		
7	Which method(s) should facilities use to clean reusable medical devices at the location of processing?	<ol style="list-style-type: none"> <li>1. At the location of processing by sterilization or HLD, follow the reusable medical device's MIFU, including specified steps such as placing the device in the open position, disassembling the device and its accessories, actuating it, and cleaning it to remove soils from surfaces.</li> <li>2. After manual cleaning, if recommended and in accordance with the device's MIFU, clean reusable medical devices with:</li> </ol>

		<ol style="list-style-type: none"> <li>a. A mechanical washer <i>OR</i></li> <li>b. A mechanical washer with an ultrasonic cleaning phase.</li> </ol>
8	Are there any reusable medical devices that should be segregated from others for processing?	Facilities do not need to segregate reusable medical devices for infection prevention reasons, with the exception of potentially prion-contaminated reusable medical devices. Prions are out of scope for this document.
9	What type of water should be used for rinsing medical devices in a mechanical washer?	<ol style="list-style-type: none"> <li>1. Verify that all water supplied to the facility meets the requirements described in the mechanical washer's MIFU.</li> <li>2. Ensure that the water used in processing is part of the facility's water management plan.</li> </ol>
10	What methods should facilities use to verify that mechanical washers are working effectively?	<ol style="list-style-type: none"> <li>1. To confirm that mechanical washers adequately perform all stages of the cleaning cycle, perform cleaning verification testing per the equipment's MIFU.</li> <li>2. Record the results when the equipment is installed, after major repairs, and each day that it is used.</li> <li>3. Incorporate verification tests for mechanical washers that: <ol style="list-style-type: none"> <li>a. Monitor at the point-of-use</li> <li>b. Generate immediate results</li> <li>c. Indicate that all stages in the mechanical washer's cleaning cycle meet the mechanical cleaning parameters.</li> </ol> </li> </ol>
11	Should healthcare facilities test the quality of water used for medical device processing at the point of use?	<p>Beyond the testing required to support a facility's water management program, no recommendation can be made for point-of-use water quality testing for reducing the risk of transmission of infectious pathogens, except:</p> <ol style="list-style-type: none"> <li>1. When indicated by the MIFU</li> <li>2. When recommended by the local or state public health department</li> <li>3. In the setting of outbreak investigation when a water source is suspected</li> <li>4. When investigating staining, damage, or residue on processed medical devices.</li> </ol>
12	What additional methods, if any, are recommended to assess the cleanliness of reusable medical devices prior to sterilization and HLD?	<ol style="list-style-type: none"> <li>1. Beyond external visual inspection (see 42), no recommendation can be made for additional methods for cleaning verification to prevent transmission events.</li> <li>2. No recommendation can be made for the use of surrogate tests to detect residual organic material (e.g., ATP, protein, or heme) to assess adequacy of cleaning. Currently, these tests are not correlated with reduction of risk for microbial contamination or transmission of infection.</li> <li>3. For training purposes, facilities may include surrogate tests for medical devices that have a higher incidence of cleaning failure, such as lumened endoscopes, for training purposes.</li> </ol>
<b>Sterilization</b>		
13	What should facilities consider when evaluating a sterilization method for a new device or when switching from one process of sterilization to another process of sterilization?	<ol style="list-style-type: none"> <li>1. Ensure the change(s) are permitted by the MIFU.</li> <li>2. Review the implications of changing methods (e.g., effectiveness, materials compatibility, packaging, detergent or sterilant residues, absorption of sterilant by packaging, moisture, rust).</li> </ol>
14	How should facilities monitor the effectiveness of sterilization?	<ol style="list-style-type: none"> <li>1. Monitor sterilizing conditions using a combination of physical, chemical, and biological indicators (see <i>Table 6</i>).</li> <li>2. At minimum, include physical and chemical indicators for all sterilizations, with regular addition of biological indicators.</li> <li>3. Always include biological indicators and Type 5 chemical indicators for sterilization of implants.</li> </ol>
15	What should be done if one or more methods used to monitor the effectiveness of sterilization indicate failure?	<ol style="list-style-type: none"> <li>1. If a failure is identified by a positive biological indicator, immediately retrieve and reprocess all affected devices back to the last negative result.</li> <li>2. If a failure is identified by a physical or chemical indicator, consider affected reusable medical devices to be not sterile and embargo them while the cause of the failure is assessed.</li> </ol>

		<ol style="list-style-type: none"> <li>3. Develop processes to investigate root causes of indicator failures.</li> <li>4. Take a sterilizer out of service during the investigation of a failure.</li> <li>5. Notify IPC and the areas using them for appropriate management (see 14, 16, and Table 7) if reusable medical devices have been used before the failure was identified.</li> </ol>
16	What steps should a facility take after identifying a processing failure or a potential transmission event?	<ol style="list-style-type: none"> <li>1. Immediately remove improperly processed reusable medical devices from use.</li> <li>2. Cease using any processing equipment suspected of not functioning properly.</li> <li>3. Follow an organized, timely process using available data to assess the potential infection risk to patients from the processing failure.</li> <li>4. With guidance of IPC experts, involve partners, including public health authorities when appropriate, to determine and carry out follow-up actions.</li> <li>5. Develop and implement preventive strategies based on the lessons learned from the failure in processing or identification of a potential transmission event.</li> </ol>
<b>Immediate use steam sterilization</b>		
17	Is there risk to immediate use steam sterilization (IUSS) when properly performed?	<ol style="list-style-type: none"> <li>1. Although IUSS is an effective method of sterilization when properly performed, facilities should not routinely use IUSS.</li> <li>2. Design and implement processes that ensure that when IUSS is used: <ol style="list-style-type: none"> <li>a. IUSS is performed by trained, competent personnel (see 43) in accordance with the reusable medical device or implant's MIFU</li> <li>b. The sterilizer and the device or implant's MIFUs include instructions for IUSS</li> <li>c. The device or implant is placed in container validated for IUSS and legally marketed per FDA for this purpose</li> <li>d. The sterilization process is verified to be successful according to the appropriate indicator for the device or implant (see 14 and Table 6)</li> <li>e. Measures are taken to prevent contamination of the device or implant during removal from the sterilizer and transfer to the sterile field</li> <li>f. Before patient care, the device or implant that was subjected to IUSS is cooled to body temperature without compromising sterility.</li> </ol> </li> </ol>
18	When may IUSS be used?	<ol style="list-style-type: none"> <li>1. As a last resort when the standard sterilization process cannot be performed (e.g., intraoperative contamination of a unique device with no replacement available) and the risk of a delayed procedure exceeds risk of using IUSS, provided that all processing steps prior to IUSS are done according to the MIFU.</li> <li>2. Only when the devices or implants are heat-stable, the MIFU provides instructions for IUSS, and the facility has a process in place that involves IPC, patient safety, risk management/legal, and appropriate clinicians to evaluate whether benefits exceed the risks of using the implant or device.</li> </ol>
<b>High-level disinfection</b>		
19	How should portions of a semi-critical device that do not come in contact with mucous membranes or non-intact skin (e.g., cables, connectors) be cleaned and disinfected?	Clean and low-level disinfect portions of a device that do not come in contact with mucous membranes or non-intact skin (e.g., cables, connectors) according to the device's MIFU.
20	Does a single use sheath or probe cover allow for low-level disinfection instead of HLD?	Perform HLD on a semi-critical reusable medical device that was used with a sheath. Unless otherwise specified by the MIFU, sheaths do not eliminate the need for HLD for a semi-critical reusable medical device.

21	Is sterilization or HLD needed for ultrasound probes used for percutaneous procedures on intact skin (e.g., central line placement, paracentesis, biopsy)?	<ol style="list-style-type: none"> <li>1. Sterilization or HLD is not required for ultrasound probes applied to intact skin for the intended use of guiding percutaneous procedures, such as central line placement, amniocentesis, or biopsy.</li> <li>2. Clean and low-level disinfect these ultrasound probes, following the MIFU.</li> </ol>
22	How should non-lumened devices be stored following HLD?	<ol style="list-style-type: none"> <li>1. Inspect non-lumened devices that have undergone HLD for damage, dry them, and store them in a manner that reduces the risk of contamination, in accordance with the MIFU.</li> <li>2. Store ready-for-use reusable medical devices separate from contaminated (used) devices and ensure they are easily distinguishable (e.g., prominently labeled as “patient ready”) from those that are not ready for use.</li> </ol>
<i>HLD of lumened devices</i>		
23	What are the requirements for adequate germicide flow?	<ol style="list-style-type: none"> <li>1. Ensure that germicide flows through lumened reusable medical devices’ channels unimpeded with appropriate flow dynamics. The physical force of fluid through the channels aids in removal of microorganisms and may aid in the removal of biofilms.</li> <li>2. Positive pressure is required, but no recommendation can be made for the minimum amount of pressure. Passive flow is insufficient for removal of microorganisms.</li> </ol>
24	Is there a preferred drying method following HLD of a lumened device?	<ol style="list-style-type: none"> <li>1. Dry exterior surfaces according to the specifications in the MIFU (e.g., cloth that is clean or sterile, low-linting, or lint-free).</li> <li>2. Use pressure-regulated instrument air or HEPA-filtered air to dry the lumens of endoscopes following HLD for the time specified by the device’s MIFU.</li> <li>3. Always dry a device following HLD, even if the device is planned for immediate use.</li> </ol>
25	How should lumened reusable medical devices be stored following HLD?	<ol style="list-style-type: none"> <li>1. After HLD, store lumened reusable medical devices and their accessories in accordance with their MIFUs. This includes but may not be limited to: <ol style="list-style-type: none"> <li>a. Completely drying lumened reusable medical devices and accessories (see 24)</li> <li>b. Storing lumened devices and accessories in a manner that protects them from contamination and damage, in accordance with their MIFUs</li> <li>c. Placing lumened devices in the position indicated by their MIFUs (i.e., vertical or horizontal position) and the validated design of the storage cabinet. If placed in a vertical position, the device should not be coiled and should not touch the bottom of the cabinet.</li> </ol> </li> <li>2. Place storage cabinets in a secure location that protects their contents from contamination and damage.</li> <li>3. Ensure storage cabinets are kept clean and dry.</li> <li>4. Adequately maintain storage cabinets per their MIFUs.</li> <li>5. No recommendation can be made for the use of drying cabinets to prevent the transmission of infections.</li> </ol>
<i>Special considerations for HLD</i>		
26	When and how should lubricating and defoaming agents be used for medical devices?	<ol style="list-style-type: none"> <li>1. Use lubricating or defoaming agents for medical devices when clinically needed and as permitted and specified by the MIFU.</li> <li>2. Preferentially choose water-soluble agents over non-water-soluble agents, if permitted by the MIFU.</li> <li>3. Prior to processing, clean the device after use to remove lubricating and defoaming agents in accordance with the MIFU.</li> <li>4. For lumened, semi-critical reusable medical devices, as permitted by the MIFU: <ol style="list-style-type: none"> <li>a. Minimize the use of non-water-soluble defoaming agents consistent with the amount clinically needed for a successful completion of the procedure</li> </ol> </li> </ol>

		<p>b. When the device is used with simethicone:</p> <ol style="list-style-type: none"> <li>i. Apply the minimum amount of simethicone required for a successful procedure</li> <li>ii. Follow the MIFU for how to add simethicone to the device</li> <li>iii. If the MIFU does not specify the process for adding simethicone to the device, ideally deliver simethicone directly into the working channel, rather than into the irrigation water bottle</li> <li>iv. After use, clean the device as specified by the MIFU.</li> </ol>
27	Does HLD inactivate human papilloma virus, multidrug-resistant bacteria, and multidrug-resistant fungi (e.g., <i>C. auris</i> )?	HLD, when properly performed, is shown to be effective against human papilloma virus (HPV), multidrug-resistant bacteria (e.g., carbapenem-resistant <i>Enterobacteriales</i> , and multidrug-resistant fungi (e.g., <i>C. auris</i> ).
28	Is automated processing superior to manual HLD?	<ol style="list-style-type: none"> <li>1. Automated processing is preferred over manual HLD because it has been shown to result in more reliable processing and to achieve higher microbe elimination than manual HLD, and the use of automated processing systems may reduce exposure of HCP to chemicals.</li> <li>2. Maintain automated processing systems according to their MIFUs.</li> </ol>
29	What should facilities monitor to ensure that HLD conditions are achieved?	Monitor compliance with MIFU, including the concentration of the active ingredient(s) in a liquid chemical sterilant or high-level disinfectant (i.e., the minimum effective concentration (MEC) and minimum recommended concentration [MRC]), temperature, and time. Considerations for types of indicators and their parameters are provided in <i>Table 6</i> .
30	Should facilities routinely use microbial cultures to assess the effectiveness of HLD for lumened and non-lumened devices?	<ol style="list-style-type: none"> <li>1. No recommendation can be made for routinely using microbial cultures to assess the effectiveness of the HLD process.</li> <li>2. Facilities may consider culture-based methods as part of a quality assurance (QA) program and for outbreak investigations.</li> </ol>
<b>Handling reusable medical devices after HLD</b>		
31	After processing, how should reusable medical devices that have undergone HLD be handled for storage?	<ol style="list-style-type: none"> <li>1. Follow the MIFU for how to handle reusable medical devices that have undergone HLD and are ready for storage.</li> <li>2. Perform hand hygiene before handling devices that have undergone HLD.</li> <li>3. No recommendation can be made for the use of gloves in addition to hand hygiene to reduce the risk of transmission of infectious agents to patients. Gloves are not a substitute for hand hygiene.</li> </ol>
32	Is there a maximum time that properly processed non-lumened and lumened devices can be stored, after which facilities should repeat HLD to reduce the risk of transmission of infection?	<ol style="list-style-type: none"> <li>1. No recommendation can be made for a maximum time after which facilities should repeat HLD for devices, including lumened devices, if a maximum time is not specified by the MIFU and the devices have been properly cleaned, processed, and stored without evidence of breaches or events leading to potential contamination (e.g., flood, non-contained construction).</li> <li>2. If a maximum time is not specified by the device MIFU, a facility may use a risk assessment to determine whether to use a time or event-based method for defining how long to store non-lumened and lumened devices.</li> <li>3. If there is evidence of contamination, repeat HLD, processing the device in accordance with the MIFU.</li> </ol>
<b>Augments and alternatives to HLD</b>		
33	Should facilities perform additional cycles of HLD (e.g., double HLD or “dHLD”) to reduce the risk of residual contamination?	No recommendation can be made for the use of more than one cycle of HLD for the purpose of reducing microbial contamination.
34	Instead of HLD, should certain semi-critical devices preferentially be sterilized?	<ol style="list-style-type: none"> <li>1. When sterilization technologies are shown to be effective in clinical settings and cycle specifications are validated and included in the MIFU, facilities should begin developing an institutional process for converting from HLD to sterilization for semi-critical reusable medical devices that are associated with high risk of transmission of infection to patients.</li> </ol>

		2. Facilities may choose to evaluate sterilization along with other alternatives to HLD, e.g., use of sterile, single use devices (see 36) or alternative therapeutic or diagnostic modalities as appropriate, considering infection outcomes, clinical functionality of the devices, feasibility, and patients' access to care.
35	Should facilities choose reusable or sterile, single use duodenoscope components (e.g., distal endcaps, elevator mechanisms) and accessories (e.g., biopsy port caps, valves, and buttons)?	<ol style="list-style-type: none"> <li>1. Choose duodenoscope designs that have sterile, single use components and accessories to lower the risk of transmission of infection.</li> <li>2. Use endoscope components and accessories that are compatible with the endoscope, recommended by the endoscope's MIFU, and are legally marketed per FDA.</li> </ol>
36	When available and feasible, should facilities use sterile, single use endoscopes?	Facilities may choose sterile, single use endoscopes to eliminate the risk of transmission of pathogens from the device to patients, especially when the available resources (physical space, expertise, training, and staffing) do not support processing.
<b>Investigational devices</b>		
37	How should facilities process critical or semi-critical investigational reusable medical devices?	<ol style="list-style-type: none"> <li>1. Only use investigational devices following: <ol style="list-style-type: none"> <li>a. Issuance by FDA of an investigational device exemption (IDE) or approval of an investigational new drug (IND) application. Process these devices using the instructions approved with the FDA IDE or IND, OR</li> <li>b. Approval by the facility's Institutional Review Board (IRB) with determination that the device is "minimal risk" and with approval of cleaning and sterilization or disinfection instructions by both IPC experts and the IRB.</li> </ol> </li> <li>2. When using investigational devices in accordance with either of the options described above, involve IPC in review and approval of processing protocols.</li> </ol>
38	How should 3-dimensional-printed (i.e., 3D-printed or additively manufactured) critical or semi-critical reusable medical devices be processed?	<ol style="list-style-type: none"> <li>1. Ensure that devices that are 3D-printed are legally marketed per FDA.</li> <li>2. Follow the validated processing instructions provided in the MIFU.</li> <li>3. When a 3D-printed device is considered investigational, follow the requirements for investigational devices (see 37).</li> </ol>
<b>Tracking reusable medical devices</b>		
39	What is the best method for tracking reusable medical devices' preventative and interval maintenance?	<ol style="list-style-type: none"> <li>1. Use electronic tracking for reusable medical devices' preventative and interval maintenance by the manufacturer. If electronic tracking is not feasible, records may be kept on paper.</li> <li>2. Adhere to recordkeeping practices per state and local requirements.</li> </ol>
40	Should a facility replace a reusable medical device (e.g., endoscope) with a new device based on time since its initial use, its last maintenance, or the number of uses?	<ol style="list-style-type: none"> <li>1. No recommendation can be made for when to replace a device with a new device.</li> <li>2. Follow the device's MIFU for the service life of the device, including requirements for preventive and interval maintenance.</li> <li>3. Facilities should not use any devices with known or suspected damage for patient care.</li> </ol>
41	Which types of reusable medical devices should facilities routinely track to the patient level?	<ol style="list-style-type: none"> <li>1. Facilities should perform risk assessments to identify the reusable medical devices that should be tracked, focusing on the reusable medical devices that have a high risk for processing failure and transmission of infection (e.g., duodenoscopes, bronchoscopes).</li> <li>2. It is at the discretion of the facility to expand tracking beyond the highest risk devices.</li> </ol>

		3. No recommendation can be made for implementing tracking to reduce the risk of transmission or to improve HCP compliance with processing steps, though tracking often is necessary to effectively respond to failures in processing, outbreaks, and product recalls.
<b>Approaches to implementation</b>		
42	What visual inspection methods are recommended to ensure debris has been removed?	<p>No standardized and readily implementable methods exist for routine, internal (e.g., endoscope channels) visual inspection of reusable medical devices; however:</p> <ol style="list-style-type: none"> <li>1. Visually inspect reusable medical devices at various stages for retained debris (prior to sterilization or HLD, after HLD, and before use) per the MIFU. Specifications may include the use of lighted magnification to improve the external visualization of reusable medical devices.</li> <li>2. Send for repair or properly discard any reusable medical devices found to be damaged. Damage can impair function, cleaning, sterilization, and HLD.</li> <li>3. If a reusable medical device is found to have retained debris, treat it according to the MIFU and reprocess it.</li> <li>4. If a lumened device is found to have retained debris that cannot be adequately removed: <ol style="list-style-type: none"> <li>a. Do not proceed with reprocessing</li> <li>b. Return the device to the manufacturer for further assessment.</li> </ol> </li> <li>5. When the manufacturer returns the reusable medical device after inspection or repair, follow the MIFU for returning the device to service.</li> <li>6. No recommendation can be made for the use of borescopic examination to assess the integrity of lumened devices before processing.</li> </ol>
43	Should HCP participating in sterilization or HLD be educated, trained, and assessed for competency?	<ol style="list-style-type: none"> <li>1. Ensure that all HCP are educated, trained, and assessed for competency in sterilization and/or HLD based on their job responsibilities: <ol style="list-style-type: none"> <li>a. Before working independently</li> <li>b. When new equipment or when new sterilization or HLD methods are implemented</li> <li>c. When processes are changed.</li> </ol> </li> <li>2. No recommendation can be made for the optimal frequency of ongoing education, training, and competency assessments for HCP who are engaged in sterilization and HLD; however, facilities should adhere to specific requirements from manufacturers, state and local regulatory agencies, and accrediting organizations. Absent specific requirements, facilities should establish their own policies.</li> <li>3. No recommendation can be made for the use of periodic audits to assure that HCP are compliant in performing all steps in the MIFU.</li> </ol>
44	What measures reduce the risk of inadequate processing in the implementation of sterilization and HLD?	<ol style="list-style-type: none"> <li>1. Review the factors described in the peer-reviewed literature that contribute to common failures in sterilization and HLD. These include the environment where HLD and sterilization activities occur, organizational processes, and individual factors (see <i>Table 7</i>).</li> <li>2. Implement effective interventions and best practices to reduce the risk of failure.</li> </ol>
45	Should facilities use a centralized or decentralized processing structure?	No recommendation can be made for a centralized or a decentralized processing structure; however, facilities should assess the role of these processing structures in minimizing the risk of processing failures and risks to patients and HCP.

## Table 2. Terminology and definitions

Term used in guidance	Definition
Critical water <sup>2</sup>	<ul style="list-style-type: none"> <li>As defined by AAMI ST108<sup>2</sup>, critical water meets specific requirements for pH, total alkalinity, bacteria, endotoxin, total organic carbon, color and turbidity, and ionic contaminant parameters.</li> <li>Per AAMI, this water is mainly used for the final rinse after HLD, the final rinse of critical devices prior to sterilization, and feedwater for process steam production.<sup>2</sup></li> <li>Reverse osmosis is a common method used to prepare water to create critical water.</li> </ul>
Automated endoscope reprocessor (AER)	<ul style="list-style-type: none"> <li>As defined by FDA, AERs are devices widely used in healthcare settings to process endoscopes, such as duodenoscopes, and endoscope accessories.</li> <li>Designed to kill microorganisms in or on reusable endoscopes by exposing their outside surfaces and interior channels to high level disinfectant or liquid chemical sterilant solutions.</li> <li>Class II devices cleared through the premarket notification [510(k)] pathway.<sup>3</sup></li> </ul>
Critical, semi-critical, and non-critical items (determined by use of item, not the item itself) per the Spaulding Classification	<ul style="list-style-type: none"> <li>Critical: reusable medical devices that enter sterile issue or body cavities, or that have contact with the vascular system</li> <li>Semi-critical: reusable medical devices that encounter mucous membranes or non-intact skin</li> <li>Non-critical: reusable medical devices that encounter intact skin</li> </ul>
Implant	Per FDA, implants devices or tissues placed inside or on the surface of the body.
Intrinsic vs. extrinsic contamination	<ul style="list-style-type: none"> <li>Intrinsic contamination: occurs before an object/device enters the medical facility, most commonly at the manufacturer's site</li> <li>Extrinsic contamination: occurs during storage, manipulation, or prior to use at the medical facility</li> </ul>
Indicators: physical, chemical, and biological	See <i>Table 6</i>
Point-of-use treatment (may also be described as prior to sterilization or HLD; pre-cleaning; point-of-use cleaning)	At the location where a reusable medical device was used, removal of gross soil and treatment of item with appropriate solution(s) per the MIFU to prepare the device for sterilization or HLD.
Processing vs. reprocessing	<ul style="list-style-type: none"> <li>Processing: the entire HLD or sterilization process</li> <li>Reprocessing: processing again following failure of initial processing</li> </ul>
Reusable medical devices	Equipment used by medical personnel during patient care that when properly processed may be used for another patient.
Validation	Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. <sup>4</sup>
Verification	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. <sup>4</sup>

## Table 3. Scope

<p>Not in scope and not included (major topics; list is not exhaustive)</p>	<ul style="list-style-type: none"> <li>• Germicides that are antiseptics or preservatives</li> <li>• Sterilization or disinfection of human or animal derived organs or tissues</li> <li>• Sterilization and disinfection of dental equipment and water lines</li> <li>• Sterilization or disinfection of items possibly contaminated with prions</li> <li>• Management of devices or instruments that were contaminated with hazardous chemicals or radioactive substances</li> <li>• Sterilization or disinfection of items used in veterinary medicine</li> <li>• Devices or products that cannot be legally marketed per FDA or are not approved by EPA</li> <li>• Low level disinfection and environmental disinfection</li> <li>• Environmental design/room design outside of factors associated with sterilization or high-level disinfection</li> <li>• Issues resulting from public health boil water advisories or loss of water pressure</li> <li>• Prospective and/or retrospective surveillance outside of an outbreak to identify post-procedure clinical infection or colonization due to contaminated devices</li> <li>• Cost-benefit discussions or studies related to societal concerns (e.g., environmental impact)</li> <li>• ATP measurements beyond uses relevant to assessing cleaning prior to sterilization or high-level disinfection</li> <li>• Sterilization and disinfection of medical items including single use by large commercial vendors is not covered in this guidance document. The U.S. Food and Drug Administration provides guidance for such vendors.</li> <li>• Sterilization or disinfection of laboratory equipment</li> </ul>
<p>Topic considered settled or adequately covered elsewhere</p>	<ul style="list-style-type: none"> <li>• Healthcare personnel personal protective equipment and routine practices (PPE, hand hygiene), and general hospital design (e.g., sinks, waste disposal, showers)</li> <li>• Central vs. decentralized sterilization</li> <li>• Unidirectional workflow in processing areas</li> </ul>

## Table 4. Literature review criteria, search strategies, and PRISMA

Exclusion	<ul style="list-style-type: none"> <li>• Non-English language</li> <li>• Articles without abstracts or full text</li> <li>• Non-peer reviewed papers (e.g., scientific abstracts)</li> <li>• Non-human studies</li> <li>• Excluded commentaries, editorials, and letters</li> <li>• <a href="#">Devices or products that cannot be legally marketed per FDA</a></li> <li>• No data on sterilization or HLD (e.g., antiseptics or LLD)</li> <li>• Commentaries without original data</li> <li>• Review articles as a basis for a recommendation</li> <li>• Low-level disinfection (LLD)</li> <li>• Room disinfection devices (e.g., UV)</li> <li>• Industrial sterilization techniques</li> </ul>	
Inclusion	<ul style="list-style-type: none"> <li>• Sterilization or high-level disinfection techniques used in healthcare facilities, including implantable devices</li> <li>• Quality improvement articles with data</li> </ul>	
MeSH	Endoscope	No exclusions
	Equipment and Supplies; Medical device (examples)	<ul style="list-style-type: none"> <li>• Compressed air</li> <li>• Diaphragm Fitting Rings (add)</li> <li>• Endoscopes + (add nasopharyngoscope and ultrasound endoscope)</li> <li>• Ophthalmoscopes</li> <li>• Oscopes</li> <li>• Tonometers</li> <li>• Transducers</li> <li>• Hospitals, packaged (under Equipment and Supplies, Hospital)</li> <li>• information about what this is beyond hyperlinked definition</li> <li>• Nebulizers and Vaporizers (all under header)</li> <li>• Optical Devices (all under header)</li> <li>• Pessaries</li> <li>• Surgical Instruments +</li> <li>• Rectal Thermometers (add)</li> <li>• Orthopedic Fixation Devices +</li> <li>• External Fixation Devices</li> <li>• Vascular Closure Devices</li> <li>• Surgical Instruments (all under header)</li> </ul>
	Disease outbreak, infectious	<ul style="list-style-type: none"> <li>• Epidemic</li> <li>• Cluster</li> <li>• Pseudo-outbreak</li> <li>• Risk of transmission</li> <li>• Culture positivity</li> </ul>

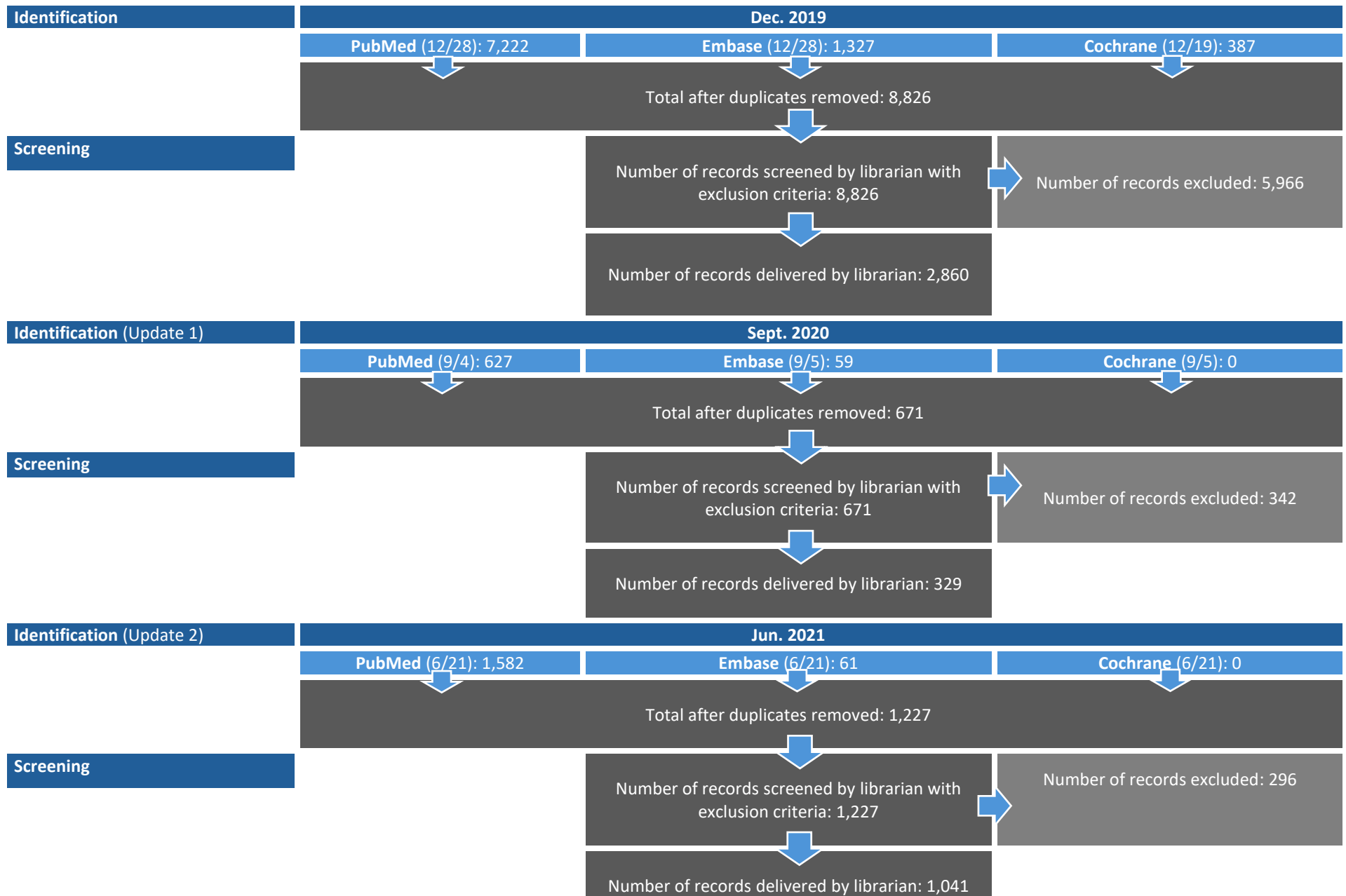
## Search strategies

#	Search strategies
1-4	((("POINT OF USE"[TIAB] OR "POINT OF CARE SYSTEMS"[MESH] OR "POINT OF CARE"[TIAB]) AND CLEANING[TW]) OR ((MANUAL CLEANING[TIAB] OR AUTOMATED CLEANING[TIAB] OR SONIC CLEANING[TIAB] OR SONICATION[MESH] OR SONIC IRRIGAT*[TIAB] OR BEDSIDE CLEANING[TIAB]) AND (((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW]))) OR (PRE-CLEANING[TIAB] OR PRECLEANING[TIAB]))
5, 10-17, 21, 24-27, 29, 30-31, 34-35, 38, 40-44, 53-57	(((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW]))) AND (((("OTOSCOPES"[MESH] OR OTOSCOPE*[TIAB] OR "OPHTHALMOSCOPES"[MESH] OR OPHTHALMOSCOPE*[TIAB] OR FUNDUSCOPE*[TIAB] OR RETINOSCOPE*[TW] OR SLIT LAMP*[TW] OR NASOENDOSCOPE*[TIAB] OR ANGIOSCOPE*[TW] OR ARTHROSCOPE*[TW] OR BRONCHOSCOPE*[TW] OR COLPOSCOPE*[TW] OR CULDOSCOPE*[TW] OR CYSTOSCOPE*[TW] OR COLONOSCOPE*[TW] OR DUODENOSCOPE*[TW] OR ESOPHAGOSCOPE*[TW] OR GASTROSCOPE*[TW] OR PROCTOSCOPE*[TW] OR FETOSCOPE*[TW] OR HYSTEROSCOPE*[TW] OR LAPAROSCOPE*[TW] OR LARYNGOSCOPES*[TW] OR MEDIASTINOSCOPES[TW] OR NEUROENDOSCOPE*[TW] OR THORACOSCOPE*[TW] OR URETEROSCOPE*[TW]) OR (SIGMOIDOSCOPE*[TW]) OR ("ENDOSONOGRAPHY"[MESH] OR ENDOSONOGRAPH*[TIAB] OR ECHO ENDOSONOGRAPH*[TIAB] OR ENDOSCOPIC ULTRASONOGRAPH*[TIAB] OR ULTRASONIC ENDOSCOPE*[TIAB] OR ECHO ENDOSCOPE*[TIAB]) OR (ULTRASOUND ENDOSCOPE*[TIAB] OR ULTRASOUND PROBE*[TIAB] OR ENDOVAGINAL PROBE*) OR (NASOPHARYNGOSCOPE*[TIAB] OR NASOENDOSCOPE*[TIAB]) OR ("ENDOSCOPES"[MESH] OR ENDOSCOPE*[TIAB] OR ENDOSCOPIC INSTRUMENT*[TIAB] OR ENDOSCOPY/INSTRUMENTATION[MESH] OR LAPAROSCOPY/INSTRUMENTATION[MESH] OR ENDOCAVITARY PROBE*[TIAB])) OR ("SURGICAL INSTRUMENTS"[MESH] OR SURGICAL INSTRUMENT*[TIAB] OR "COMPRESSED AIR"[MESH] OR COMPRESSED AIR[TIAB] OR DIAPHRAGM FITTING RING*[TIAB] OR ((NEBULIZERS AND VAPORIZERS"[MESH] OR NEBULIZER*[TIAB] OR NEBULISER*[TIAB] OR VAPORIZER*[TIAB] OR VAPORISER*[TIAB] OR ATOMIZER*[TIAB] OR ATOMISER*[TIAB] OR INHALOR*[TIAB] OR INHALATOR*[TIAB] OR INHALATION DEVICE*[TIAB]) OR ("INHALATION SPACERS"[MESH] OR INHALATION SPACER*[TIAB])) OR (TRANSDUCER*[TW]) OR ("TONOMETRY, OCULAR"[MESH] OR TONOMET*[TIAB]) OR ("OBSTETRICAL FORCEPS"[MESH] OR FORCEPS[TIAB]) OR (FORCEP[TIAB] OR SPECULUM*[TIAB] OR SURGICAL CLAMP*[TIAB] OR SURGICAL CLIP*[TIAB] OR SURGICAL PLUG*[TIAB] OR SURGICAL SCISSORS*[TIAB] OR TROCAR*[TIAB] OR SURGICAL VALVE*[TIAB] OR TANTALUM CLIP*[TIAB] OR SURGICAL HOOK*[TIAB]) OR ("SURGICAL STAPLERS"[MESH] OR SURGICAL STAPLER*[TIAB]) OR ("THERMOMETERS"[MESH] AND RECTAL*[TIAB]) OR RECTAL THERMOMETER*[TIAB]) OR ("ORTHOPEDIC FIXATION DEVICES"[MESH:NOEXP] OR ORTHOPEDIC FIXATION DEVICE*[TIAB] OR ORTHOPAEDIC FIXATION DEVICE*[TIAB]) OR ("EXTERNAL FIXATORS"[MESH:NOEXP] OR EXTERNAL FIXATOR*[TIAB] OR EXTERNAL FIXATION DEVICE*[TIAB]) OR ("VASCULAR CLOSURE DEVICES"[MESH] OR VASCULAR CLOSURE DEVICE*[TIAB] OR VASCULAR CLOSURE PATCH*[TIAB] OR CATHETERIZATION CLOSURE DEVICE*[TIAB]) OR MEDICAL DEVICE*[TIAB] OR EQUIPMENT CONTAMINATION[MESH] OR EQUIPMENT REUSE[MESH] OR "OPTICAL DEVICES"[MESH] OR OPTICAL DEVICE*[TIAB] OR LASER*[TW]))
6	((SOIL REMOVAL[TIAB] OR SOIL TEST*[TIAB] OR DEBRIS REMOVAL[TIAB] OR ULTRASONOGRAPH*[TW] OR ULTRASONIC*[TW] OR ULTRA-SONIC*[TIAB] OR ULTRASOUND*[TIAB] OR ULTRASOUND*[TIAB] OR CAVITATION[TIAB] OR AER[TIAB] OR AUTOMATED[TW]) AND (((("OTOSCOPES"[MESH] OR OTOSCOPE*[TIAB] OR "OPHTHALMOSCOPES"[MESH] OR OPHTHALMOSCOPE*[TIAB] OR FUNDUSCOPE*[TIAB] OR RETINOSCOPE*[TW] OR SLIT LAMP*[TW] OR NASOENDOSCOPE*[TIAB] OR ANGIOSCOPE*[TW] OR ARTHROSCOPE*[TW] OR BRONCHOSCOPE*[TW] OR COLPOSCOPE*[TW] OR CULDOSCOPE*[TW] OR CYSTOSCOPE*[TW] OR COLONOSCOPE*[TW] OR DUODENOSCOPE*[TW] OR ESOPHAGOSCOPE*[TW] OR GASTROSCOPE*[TW] OR PROCTOSCOPE*[TW] OR FETOSCOPE*[TW] OR HYSTEROSCOPE*[TW] OR LAPAROSCOPE*[TW] OR LARYNGOSCOPES*[TW] OR MEDIASTINOSCOPES[TW] OR NEUROENDOSCOPE*[TW] OR THORACOSCOPE*[TW] OR URETEROSCOPE*[TW]) OR (SIGMOIDOSCOPE*[TW]) OR ("ENDOSONOGRAPHY"[MESH] OR ENDOSONOGRAPH*[TIAB] OR ECHO ENDOSONOGRAPH*[TIAB] OR ENDOSCOPIC ULTRASONOGRAPH*[TIAB] OR ULTRASONIC ENDOSCOPE*[TIAB] OR ECHO ENDOSCOPE*[TIAB]) OR (ULTRASOUND ENDOSCOPE*[TIAB] OR ULTRASOUND PROBE*[TIAB] OR ENDOVAGINAL PROBE*) OR (NASOPHARYNGOSCOPE*[TIAB] OR NASOENDOSCOPE*[TIAB]) OR ("ENDOSCOPES"[MESH] OR ENDOSCOPE*[TIAB] OR ENDOSCOPIC INSTRUMENT*[TIAB] OR ENDOSCOPY/INSTRUMENTATION[MESH] OR LAPAROSCOPY/INSTRUMENTATION[MESH] OR ENDOCAVITARY PROBE*[TIAB])) OR ("SURGICAL INSTRUMENTS"[MESH] OR SURGICAL INSTRUMENT*[TIAB] OR "COMPRESSED AIR"[MESH] OR COMPRESSED AIR[TIAB] OR DIAPHRAGM FITTING RING*[TIAB] OR ((NEBULIZERS AND VAPORIZERS"[MESH] OR NEBULIZER*[TIAB] OR NEBULISER*[TIAB] OR VAPORIZER*[TIAB] OR VAPORISER*[TIAB] OR ATOMIZER*[TIAB] OR ATOMISER*[TIAB] OR INHALOR*[TIAB] OR INHALATOR*[TIAB] OR INHALATION DEVICE*[TIAB]) OR ("INHALATION SPACERS"[MESH] OR INHALATION SPACER*[TIAB])) OR (TRANSDUCER*[TW]) OR ("TONOMETRY, OCULAR"[MESH] OR TONOMET*[TIAB]) OR ("OBSTETRICAL FORCEPS"[MESH] OR FORCEPS[TIAB]) OR (FORCEP[TIAB] OR SPECULUM*[TIAB] OR SURGICAL CLAMP*[TIAB] OR SURGICAL CLIP*[TIAB] OR SURGICAL PLUG*[TIAB] OR SURGICAL SCISSORS*[TIAB] OR TROCAR*[TIAB] OR SURGICAL VALVE*[TIAB] OR TANTALUM CLIP*[TIAB] OR SURGICAL HOOK*[TIAB]) OR ("SURGICAL STAPLERS"[MESH] OR SURGICAL STAPLER*[TIAB]) OR ("THERMOMETERS"[MESH] AND RECTAL*[TIAB]) OR RECTAL THERMOMETER*[TIAB]) OR ("ORTHOPEDIC FIXATION DEVICES"[MESH:NOEXP] OR ORTHOPEDIC FIXATION DEVICE*[TIAB] OR ORTHOPAEDIC FIXATION DEVICE*[TIAB]) OR ("EXTERNAL FIXATORS"[MESH:NOEXP] OR EXTERNAL FIXATOR*[TIAB] OR EXTERNAL FIXATION DEVICE*[TIAB]) OR ("VASCULAR CLOSURE DEVICES"[MESH] OR VASCULAR CLOSURE DEVICE*[TIAB] OR VASCULAR CLOSURE PATCH*[TIAB] OR CATHETERIZATION CLOSURE DEVICE*[TIAB]) OR MEDICAL DEVICE*[TIAB] OR EQUIPMENT CONTAMINATION[MESH] OR EQUIPMENT REUSE[MESH] OR "Optical Devices"[Mesh] OR OPTICAL DEVICE*[TIAB] OR LASER*[TW])) AND CLEAN*)) OR (AUTOMATIC WASHER*[TIAB]) OR (SOIL CHALLENGE*[TIAB]))
7	(VISUAL INSPECTION*[TIAB] OR BOROSCOPE*[TIAB] OR BORESCOPE*[TIAB] OR LIGHTED MAGNIF*[TIAB] OR ENHANCED VISUALIZATION[TIAB] OR AUGMENTED VISUALIZATION[TIAB]) AND (((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW])))

8	((((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW])) OR CLEANING[TIAB]) AND (PROTEIN TEST*[TW] OR "PROTEINS/ANALYSIS"[MESH] OR ADENOSINE TRIPHOSPHATE[MESH] OR ADENOSINE TRIPHOSPHATE[TW] OR ADENYLPYROPHOSPHATE[TW] OR MGATP[TW] OR MNATP[TW] OR ATRIPHOS[TW] OR CRATP[TW] OR CAATP[TW] OR ATP-MGCL2[TW] OR STRIADYNE[TW] OR LUMINESCENT MEASUREMENT*[TW] OR LUMINESCENT ASSAY*[TW] OR LUMINESCENT TECHNIQUE*[TW] OR LUMINESCENCE MEASUREMENT*[TW] OR CHEMILUMINESCENT MEASUREMENT*[TW] OR CHEMILUMINESCENT ASSAY*[TW] OR CHEMOLUMINESCENCE MEASUREMENT*[TW] OR CHEMILUMINESCENCE MEASUREMENT*[TW] OR PHOSPHORESCENT MEASUREMENT*[TW] OR PHOSPHORESCENT ASSAY*[TW] OR PHOSPHORESCENCE MEASUREMENT*[TW] OR BIOLUMINESCENT MEASUREMENT*[TW] OR BIOLUMINESCENT ASSAY*[TW] OR BIOLUMINESCENCE MEASUREMENT*[TW] OR FLUORESCENT MARKER*[TW])) OR (CLEANING VALIDATION*[TIAB] OR CLEANING VERIFICATION*[TIAB]))
9	(LUMEN[TIAB] OR LUMENS[TIAB] OR LUMINAL[TIAB] OR LUMENED[TIAB]) AND ((BRUSH*[TIAB] OR "Water Quality"[Mesh] OR WATER QUALITY[TIAB] OR POTABLE WATER[TIAB] OR STERILE WATER[TIAB] OR CRITICAL WATER[TIAB] OR FILTERED WATER[TIAB] OR RINSING[TIAB] OR DRYING[TIAB] OR SCRATCH[TIAB] OR SCRATCHES[TIAB] OR INSTRUMENT AIR[TIAB] OR INSTRUMENT GRADE AIR[TIAB] OR SOAKING[TIAB]) OR CLEANING)
12	(("ELECTRODES, IMPLANTED"[MESH] OR IMPLANTED ELECTROD*[TIAB] OR IMPLANTABLE ELECTROD*[TIAB]) OR ("DEFIBRILLATORS, IMPLANTABLE"[MESH] OR IMPLANTABLE DEFIBRILLATOR*[TIAB] OR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR*[TIAB]) OR ("BIOPROSTHESIS"[MESH] OR BIOPROSTHES*[TIAB] OR GRAFT[TIAB] OR GRAFTS[TIAB] OR XENOGRAFT*[TIAB]) OR ("EMBOLIC PROTECTION DEVICES"[MESH] OR EMBOLIC PROTECTION DEVICE*[TIAB] OR EMBOLI PROTECTION DEVICE*[TIAB] OR EMBOLISM PROTECTION DEVICE*[TIAB] OR EMBOLIC PROTECTION FILTER*[TIAB]) OR ("VENA CAVA FILTERS"[MESH] OR VENA CAVA FILTER*[TIAB] OR UMBRELLA FILTER*[TIAB]) OR ("EYE, ARTIFICIAL"[MESH] OR ARTIFICIAL EYE*[TIAB]) OR ("FIDUCIAL MARKERS"[MESH] OR FIDUCIAL MARKER*[TIAB]) OR (AQUEOUS SHUNT*[TIAB] OR AQUEOUS HUMOR SHUNT*[TIAB] OR KRUPIN VALVE*[TIAB]) OR ("HEART, ARTIFICIAL"[MESH] OR ARTIFICIAL HEART*[TIAB]) OR ("HEART-ASSIST DEVICES"[MESH] OR HEART ASSIST DEVICE*[TIAB] OR HEART ASSIST PUMP*[TIAB] OR VASCULAR ASSIST DEVICE*[TIAB] OR ARTIFICIAL VENTRICLE*[TIAB] OR VENTRICLE ASSIST DEVICE*[TIAB] OR VENTRICULAR ASSIST DEVICE*[TIAB]) OR ("INTERNAL FIXATORS"[MESH] OR INTERNAL FIXATOR*[TIAB] OR INTERNAL FIXATION DEVICE*[TIAB]) OR ("BONE NAILS"[MESH] OR BONE NAIL*[TIAB] OR BONE PIN[TIAB] OR BONE PINS[TIAB]) OR ("BONE PLATES"[MESH] OR BONE PLATE*[TIAB]) OR ("BONE SCREWS"[MESH] OR BONE SCREW*[TIAB]) OR ("PEDICLE SCREWS"[MESH] OR PEDICLE SCREW*[TIAB]) OR ("BONE WIRES"[MESH] OR BONE WIRE*[TIAB] OR KIRSCHNER WIRE*[TIAB]) OR ("SUTURE ANCHORS"[MESH] OR SUTURE ANCHOR*[TIAB] OR BONE ANCHOR*[TIAB]) OR ("LARYNX, ARTIFICIAL"[MESH] OR ARTIFICIAL LARYN*[TIAB]) OR ("PROSTHESES AND IMPLANTS"[MESH:noexp] OR IMPLANT*[TW] OR IMPLANTS[TW] OR PROSTHES*[TW]) OR ("PUNCTAL PLUGS"[MESH] OR PUNCTAL PLUG*[TIAB]) OR ("SEPTAL OCCLUDER DEVICE"[MESH] OR SEPTAL OCCLUDER*[TIAB] OR CARDIOSEAL OCCLUDER*[TIAB] OR AMPLATZER OCCLUDER*[TIAB]) OR ("STENTS"[MESH] OR STENT[TW] OR STENTS[TW]) OR ("SUBURETHRAL SLINGS"[MESH] OR SUBURETHRAL SLING*[TIAB]) OR (MALE URETHRAL SLING*[TIAB] OR MALE SLING*[TIAB] OR TRANSOBTURATOR TAPE*[TIAB] OR TRANSOBTURATOR SUBURETHRAL TAPE*[TIAB] OR TRANS-OBTURATOR TAPE*[TIAB] OR URETHRAL SLING*[TIAB] OR MIDURETHRAL SLING*[TIAB] OR MID-URETHRAL SLING*[TIAB] OR TENSIONLESS VAGINAL TAPE*[TIAB] OR TENSION-FREE VAGINAL TAPE*[TIAB]) OR ("TISSUE EXPANSION DEVICES"[MESH] OR TISSUE EXPANSION DEVICE*[TIAB] OR TISSUE EXPANDER*[TIAB]) OR ("TISSUE SCAFFOLDS"[MESH] OR TISSUE SCAFFOLD*[TIAB]) OR ("URINARY SPHINCTER, ARTIFICIAL"[MESH] OR ARTIFICIAL URINARY SPHINCTER*[TIAB] OR ARTIFICIAL GENITOURINARY SPHINCTER*[TIAB]) OR (BIONIC EYE*[TIAB])) AND ((STERILIZATION* OR STERILISATION*) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH]))
18, 21, 29-30	NON-LUMEN* [TIAB] OR NONLUMEN* [TIAB]
19	(((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW])) AND (SHEATH*[TW] OR ENDOSHEATH*[TW] OR ENDO-SHEATH*[TW] OR CONDOM COVER*[TIAB]))
20	(ULTRASOUND PROBE*[TIAB] OR ULTRASONOGRAPHY PROBE*[TIAB] OR ULTRASONOGRAPHY/INSTRUMENTATION[MH]) AND (((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW])))
19-20, 28-30	(LUMEN*[TW]) AND (((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW])))
28-39	("ANTINEOPLASTIC AGENTS"[PHARMACOLOGICAL ACTION] OR "ANTINEOPLASTIC AGENTS"[MESH] OR RADIOACTIVE DRUG*[TIAB] OR RADIOACTIVE AGENT*[TIAB] OR RADIOACTIVE MEDICATION*[TIAB] OR "CYTOTOXINS"[PHARMACOLOGICAL ACTION] OR CYTOTOXINS[MESH] OR ANTINEOPLASTIC AGENT*[TIAB] OR ANTI-NEOPLASTIC AGENT*[TIAB] OR ANTINEOPLASTIC DRUG*[TIAB] OR ANTINEOPLASTICS[TIAB] OR CHEMOTHERAPEUTIC ANTICANCER DRUG*[TIAB] OR ANTITUMOR DRUG*[TIAB] OR CANCER CHEMOTHERAPY AGENT*[TIAB] OR CHEMOTHERAPEUTIC ANTICANCER AGENT*[TIAB] OR ANTICANCER AGENT*[TIAB] OR ANTITUMOR AGENT*[TIAB]) AND (("Decontamination"[Mesh] OR DECONTAMINAT*[TIAB] OR EQUIPMENT CONTAMINATION[MH]) AND (((("OTOSCOPES"[MESH] OR OTOSCOPE*[TIAB] OR "OPHTHALMOSCOPES"[MESH] OR OPHTHALMOSCOPE*[TIAB] OR FUNDUSCOPE*[TIAB] OR RETINOSCOPE*[TW] OR SLIT LAMP*[TW] OR NASOENDOSCOPE*[TIAB] OR ANGIOSCOPE*[TW] OR ARTHROSCOPE*[TW] OR BRONCHOSCOPE*[TW] OR COLPOSCOPE*[TW] OR CULDOSCOPE*[TW] OR CYSTOSCOPE*[TW] OR COLONOSCOPE*[TW] OR DUODENOSCOPE*[TW] OR ESOPHAGOSCOPE*[TW] OR GASTROSCOPE*[TW] OR PROCTOSCOPE*[TW] OR FETOSCOPE*[TW] OR HYSTEROSCOPE*[TW] OR LAPAROSCOPE*[TW] OR LARYNGOSCOPES*[TW] OR MEDIASTINOSCOPES[TW] OR NEUROENDOSCOPE*[TW] OR THORACOSCOPE*[TW] OR URETEROSCOPE*[TW]) OR (SIGMOIDOSCOPE*[TW]) OR ("ENDOSONOGRAPHY"[MESH] OR ENDOSONOGRAPH*[TIAB] OR ECHO ENDOSONOGRAPH*[TIAB] OR ENDOSCOPIC ULTRASONOGRAPH*[TIAB] OR ULTRASONIC ENDOSCOP*[TIAB] OR ECHO ENDOSCOP*[TIAB]) OR (ULTRASOUND ENDOSCOPE*[TIAB] OR ULTRASOUND PROBE*[TIAB] OR ENDOVAGINAL PROBE*) OR (NASOPHARYNGOSCOP*[TIAB] OR NASOENDOSCOPE*[TIAB]) OR ("ENDOSCOPES"[MESH] OR ENDOSCOPE*[TIAB] OR ENDOSCOPIC INSTRUMENT*[TIAB] OR ENDOSCOPY/INSTRUMENTATION[MESH] OR

	LAPAROSCOPY/INSTRUMENTATION[MESH] OR ENDOCAVITARY PROBE*[TIAB])) OR ("SURGICAL INSTRUMENTS"[MESH] OR SURGICAL INSTRUMENT*[TIAB] OR "COMPRESSED AIR"[MESH] OR COMPRESSED AIR[TIAB] OR DIAPHRAGM FITTING RING*[TIAB] OR (("NEBULIZERS AND VAPORIZERS"[MESH] OR NEBULIZER*[TIAB] OR NEBULISER*[TIAB] OR VAPORIZER*[TIAB] OR VAPORISER*[TIAB] OR ATOMIZER*[TIAB] OR ATOMISER*[TIAB] OR INHALOR*[TIAB] OR INHALATOR*[TIAB] OR INHALATION DEVICE*[TIAB]) OR ("INHALATION SPACERS"[MESH] OR INHALATION SPACER*[TIAB])) OR (TRANSDUCER*[TW]) OR ("TONOMETRY, OCULAR"[MESH] OR TONOMET*[TIAB]) OR ("OBSTETRICAL FORCEPS"[MESH] OR FORCEPS[TIAB]) OR (FORCEP[TIAB] OR SPECULUM*[TIAB] OR SURGICAL CLAMP*[TIAB] OR SURGICAL CLIP*[TIAB] OR SURGICAL PLUG*[TIAB] OR TROCAR*[TIAB] OR SURGICAL VALVE*[TIAB] OR TANTALUM CLIP*[TIAB] OR SURGICAL HOOK*[TIAB]) OR ("SURGICAL STAPLERS"[MESH] OR SURGICAL STAPLER*[TIAB]) OR (("THERMOMETERS"[MESH] AND RECTAL*[TIAB]) OR RECTAL THERMOMETER*[TIAB]) OR ("ORTHOPEDIC FIXATION DEVICES"[MESH:NOEXP] OR ORTHOPEDIC FIXATION DEVICE*[TIAB] OR ORTHOPAEDIC FIXATION DEVICE*[TIAB]) OR ("EXTERNAL FIXATORS"[MESH:NOEXP] OR EXTERNAL FIXATOR*[TIAB] OR EXTERNAL FIXATION DEVICE*[TIAB]) OR ("VASCULAR CLOSURE DEVICES"[MESH] OR VASCULAR CLOSURE DEVICE*[TIAB] OR VASCULAR CLOSURE PATCH*[TIAB] OR CATHETERIZATION CLOSURE DEVICE*[TIAB]) OR MEDICAL DEVICE*[TIAB] OR EQUIPMENT CONTAMINATION[MESH] OR EQUIPMENT REUSE[MESH] OR "Optical Devices"[Mesh] OR OPTICAL DEVICE*[TIAB] OR LASER*[TW]))))
32-33	(DUODENOSCOPES [MESH] OR DUODENOSCOPI* [TIAB]) AND SINGLE USE* [TIAB] OR DISPOSABLE [TIAB] OR DISPOSABLE EQUIPMENT [MESH])
36	("PAPILLOMAVIRIDAE"[MESH] OR PAPILOMAVIRIDAE[TIAB] OR HUMAN PAPILOMA VIRUS*[TIAB] OR HUMAN PAPILOMA VIRUS*[TIAB] OR HUMAN PAPILOMAVIRUS VIRUS*[TIAB]) AND (((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW]))))
36	((("CANDIDA"[MESH] OR CANDIDA*[TIAB] OR MONILIA*[TIAB] OR TORULOPSIS UTILIS*[TIAB]) OR (C. AURIS[TIAB]) OR ("MYCOBACTERIUM"[MESH] OR MYCOBACTERI*[TIAB]) OR (HPV[TIAB]) OR ("ADENOVIRIDAE"[MESH] OR ADENOVIRIDAE[TIAB] OR ADENOVIRUS*[TIAB] OR ICHTADENOVIRUS*[TIAB]) OR ("NOROVIRUS"[MESH] OR NOROVIRUS*[TIAB] OR NORWALK VIRUS*[TIAB])) AND (DISINFECT*[TW] AND (RESISTANT[TW] OR RESISTANCE[TW]))
37	(WATER [MH:NOEXP] OR CRITICAL WATER* [TIAB] OR STERILE WATER [TIAB]) AND (WASHER* [TIAB] OR DISINFECTOR* [TIAB] OR WASHER-DISINFECTOR* [TIAB])
39	(RINSING [TIAB] OR RINSE* [TIAB]) AND WASHER-DISINFECTOR* [TIAB]
43-44	(MAINTENANCE*[TIAB] OR MAINTAINANCE*[TIAB]) AND ((("OTOSCOPES"[MESH] OR OTOSCOPE*[TIAB] OR "OPHTHALMOSCOPES"[MESH] OR OPHTHALMOSCOPE*[TIAB] OR FUNDUSCOPE*[TIAB] OR RETINOSCOPE*[TW] OR SLIT LAMP*[TW] OR NASOENDOSCOPE*[TIAB] OR ANGIOSCOPE*[TW] OR ARTHROSCOPE*[TW] OR BRONCHOSCOPE*[TW] OR COLPOSCOPE*[TW] OR CULDOSCOPE*[TW] OR CYSTOSCOPE*[TW] OR COLONOSCOPE*[TW] OR DUODENOSCOPE*[TW] OR ESOPHAGOSCOPE*[TW] OR GASTROSCOPE*[TW] OR PROCTOSCOPE*[TW] OR FETOSCOPE*[TW] OR HYSTEROSCOPE*[TW] OR LAPAROSCOPE*[TW] OR LARYNGOSCOPES*[TW] OR MEDIASTINOSCOPES[TW] OR NEUROENDOSCOPE*[TW] OR THORACOSCOPE*[TW] OR URETEROSCOPE*[TW] OR (SIGMOIDOSCOPE*[TW]) OR ("ENDOSONOGRAPHY"[MESH] OR ENDOSONOGRAPH*[TIAB] OR ECHO ENDOSONOGRAPH*[TIAB] OR ENDOSCOPIC ULTRASONOGRAPH*[TIAB] OR ULTRASONIC ENDOSCOPE*[TIAB] OR ECHO ENDOSCOPE*[TIAB]) OR (ULTRASOUND ENDOSCOPE*[TIAB] OR ULTRASOUND PROBE*[TIAB] OR ENDOVAGINAL PROBE*) OR (NASOPHARYNGOSCOPE*[TIAB] OR NASOENDOSCOPE*[TIAB]) OR ("ENDOSCOPES"[MESH] OR ENDOSCOPE*[TIAB] OR ENDOSCOPIC INSTRUMENT*[TIAB] OR ENDOSCOPY/INSTRUMENTATION[MESH] OR LAPAROSCOPY/INSTRUMENTATION[MESH] OR ENDOCAVITARY PROBE*[TIAB]))
45	("EQUIPMENT CONTAMINATION"[MESH] AND "CONTACT TRACING"[MESH]) OR ("TRANSMISSION"[SUBHEADING] AND (((("OTOSCOPES"[MESH] OR OTOSCOPE*[TIAB] OR "OPHTHALMOSCOPES"[MESH] OR OPHTHALMOSCOPE*[TIAB] OR FUNDUSCOPE*[TIAB] OR RETINOSCOPE*[TW] OR SLIT LAMP*[TW] OR NASOENDOSCOPE*[TIAB] OR ANGIOSCOPE*[TW] OR ARTHROSCOPE*[TW] OR BRONCHOSCOPE*[TW] OR COLPOSCOPE*[TW] OR CULDOSCOPE*[TW] OR CYSTOSCOPE*[TW] OR COLONOSCOPE*[TW] OR DUODENOSCOPE*[TW] OR ESOPHAGOSCOPE*[TW] OR GASTROSCOPE*[TW] OR PROCTOSCOPE*[TW] OR FETOSCOPE*[TW] OR HYSTEROSCOPE*[TW] OR LAPAROSCOPE*[TW] OR LARYNGOSCOPES*[TW] OR MEDIASTINOSCOPES[TW] OR NEUROENDOSCOPE*[TW] OR THORACOSCOPE*[TW] OR URETEROSCOPE*[TW] OR (SIGMOIDOSCOPE*[TW]) OR ("ENDOSONOGRAPHY"[MESH] OR ENDOSONOGRAPH*[TIAB] OR ECHO ENDOSONOGRAPH*[TIAB] OR ENDOSCOPIC ULTRASONOGRAPH*[TIAB] OR ULTRASONIC ENDOSCOPE*[TIAB] OR ECHO ENDOSCOPE*[TIAB]) OR (ULTRASOUND ENDOSCOPE*[TIAB] OR ULTRASOUND PROBE*[TIAB] OR ENDOVAGINAL PROBE*) OR (NASOPHARYNGOSCOPE*[TIAB] OR NASOENDOSCOPE*[TIAB]) OR ("ENDOSCOPES"[MESH] OR ENDOSCOPE*[TIAB] OR ENDOSCOPIC INSTRUMENT*[TIAB] OR ENDOSCOPY/INSTRUMENTATION[MESH] OR LAPAROSCOPY/INSTRUMENTATION[MESH] OR ENDOCAVITARY PROBE*[TIAB])) OR ("SURGICAL INSTRUMENTS"[MESH] OR SURGICAL INSTRUMENT*[TIAB] OR "COMPRESSED AIR"[MESH] OR COMPRESSED AIR[TIAB] OR DIAPHRAGM FITTING RING*[TIAB] OR (("NEBULIZERS AND VAPORIZERS"[MESH] OR NEBULIZER*[TIAB] OR NEBULISER*[TIAB] OR VAPORIZER*[TIAB] OR VAPORISER*[TIAB] OR ATOMIZER*[TIAB] OR ATOMISER*[TIAB] OR INHALOR*[TIAB] OR INHALATION DEVICE*[TIAB]) OR ("INHALATION SPACERS"[MESH] OR INHALATION SPACER*[TIAB])) OR (TRANSDUCER*[TW]) OR ("TONOMETRY, OCULAR"[MESH] OR TONOMET*[TIAB]) OR ("OBSTETRICAL FORCEPS"[MESH] OR FORCEPS[TIAB]) OR (FORCEP[TIAB] OR SPECULUM*[TIAB] OR SURGICAL CLAMP*[TIAB] OR SURGICAL CLIP*[TIAB] OR SURGICAL PLUG*[TIAB] OR SURGICAL SCISSORS*[TIAB] OR TROCAR*[TIAB] OR SURGICAL VALVE*[TIAB] OR TANTALUM CLIP*[TIAB] OR SURGICAL HOOK*[TIAB]) OR ("SURGICAL STAPLERS"[MESH] OR SURGICAL STAPLER*[TIAB]) OR (("THERMOMETERS"[MESH] AND RECTAL*[TIAB]) OR RECTAL THERMOMETER*[TIAB]) OR ("ORTHOPEDIC FIXATION DEVICES"[MESH:NOEXP] OR ORTHOPEDIC FIXATION DEVICE*[TIAB] OR ORTHOPAEDIC FIXATION DEVICE*[TIAB]) OR ("EXTERNAL FIXATORS"[MESH:NOEXP] OR EXTERNAL FIXATOR*[TIAB] OR EXTERNAL FIXATION DEVICE*[TIAB]) OR ("VASCULAR CLOSURE DEVICES"[MESH] OR VASCULAR CLOSURE DEVICE*[TIAB] OR VASCULAR CLOSURE PATCH*[TIAB] OR CATHETERIZATION CLOSURE DEVICE*[TIAB]) OR MEDICAL DEVICE*[TIAB] OR EQUIPMENT CONTAMINATION[MESH] OR EQUIPMENT REUSE[MESH] OR "OPTICAL DEVICES"[MESH] OR OPTICAL DEVICE*[TIAB] OR LASER*[TW])))) AND "CONTACT TRACING"[MESH])
49-52	("INSERVICE TRAINING"[MESH] OR "HEALTH PERSONNEL/EDUCATION"[MESH] OR "EDUCATION"[MESH:NOEXP] OR TRAINING[TW]) AND (((STERILIZATION*[TIAB] OR STERILISATION*[TIAB]) NOT ("STERILIZATION, TUBAL"[MESH] OR "STERILIZATION REVERSAL"[MESH] OR "STERILIZATION, INVOLUNTARY"[MESH])) OR ("STERILIZATION"[MESH] OR (STERILE PROCESSING[TIAB] OR REPROCESSING[TIAB] OR REPROCESSOR*[TIAB]) OR (DISINFECT*[TW]))))

# Preferred reporting items for systematic reviews and meta-analyses (PRISMA)



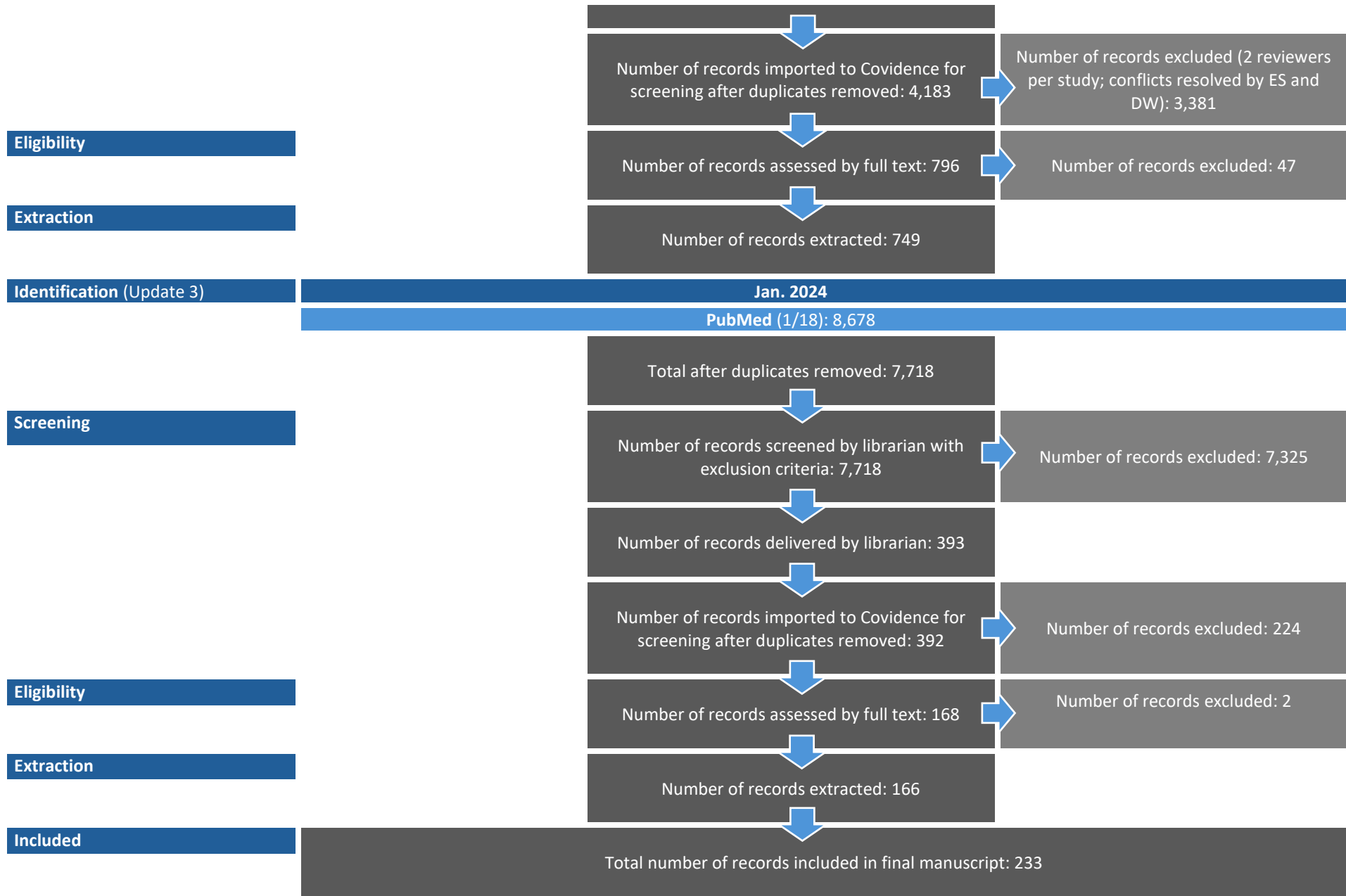


Table 5. Methods for sterilization and high-level disinfection of reusable medical devices

Process	Examples of microbes	Level of microbial inactivation	Method	Examples	Use in healthcare
Sterilization	<ul style="list-style-type: none"> <li>Highly resistant microbes</li> <li>Bacterial spores</li> </ul>	Destroys all microorganisms, including bacterial spores	High-temperature	<ul style="list-style-type: none"> <li>Steam</li> <li>Dry heat</li> </ul>	<ul style="list-style-type: none"> <li>Heat-tolerant critical and semi-critical devices/instruments</li> </ul>
			Low-temperature	Hydrogen peroxide vapor Ethylene oxide gas	Heat-sensitive critical and semi-critical devices/instruments
			Liquid immersion	Chemical sterilants (e.g., >2% glutaraldehyde)	Heat-sensitive critical and semi-critical devices/instruments that can be immersed
High-level disinfection	Moderately resistant microbes: <ul style="list-style-type: none"> <li>Parasitic oocysts</li> <li>Mycobacteria</li> <li>Nonlipid or small viruses</li> <li>Bacterial and fungal spores</li> </ul>	Destroys all microorganisms, except some bacterial spores	Heat	Pasteurization	Heat-sensitive semi-critical devices/instruments
			Liquid immersion	Chemical high-level disinfectants (e.g., >2% glutaraldehyde, hydrogen peroxide)	Heat-sensitive semi-critical items that can be immersed

## Table 6. Physical, chemical, and biological indicators for monitoring sterilization

See recommendations 14, 15 and 29. Based on standard practice, expert opinion, peer reviewed literature, federal recommendations/requirements (CDC, FDA), other professional recommendations (AORN, AAMI). Follow the device's MIFU.

Indicator	Types	Frequency	Location	Advantages and Disadvantages	
Physical: readouts from sterilizer of sterilizing conditions	<ul style="list-style-type: none"> <li>• Steam: steam-time, temperature, and/or saturated steam</li> <li>• ETO: Time, temperature, relative humidity, pressure records via cycle printouts, gauges, and/or displays</li> <li>• Hydrogen peroxide:               <ul style="list-style-type: none"> <li>○ Time, temperature, and the gas concentration</li> <li>○ Most healthcare sterilizers can monitor time, temperature, gas concentration<sup>5</sup></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• At least daily for cycle time and temperature</li> <li>• Each load that includes implantable device(s)</li> </ul>	Examination of cycle record chart, cycle printout, pressure gauge	Advantages: <ul style="list-style-type: none"> <li>• Inexpensive, easy to use, convenient</li> <li>• Immediate readout</li> <li>• Directly evaluates the sterilizing conditions (time, temperature, pressure) and indirectly evaluates the microbiologic status of the processed item</li> </ul> Disadvantages: <ul style="list-style-type: none"> <li>• Most healthcare sterilizers cannot monitor gas concentration and humidity of ETO<sup>6</sup></li> <li>• Does not demonstrate the lethality or killing power of the cycle</li> <li>• Need to maintain sterilization records for a time period compliant with standards</li> <li>• Generally, monitors 1 location in the free chamber space and not the conditions in the load or within an individual pack</li> </ul>	
Chemical (CI): heat or chemical-sensitive inks that change color or migrate when $\geq 1$ sterilization parameter is present; grouped into 6 types based on design and performance attributes <sup>6</sup>	Type 1: differentiates between processed and unprocessed loads		Type 1: outside of pack	Advantages: <ul style="list-style-type: none"> <li>• Inexpensive, easy to use, convenient</li> <li>• Immediate read-out</li> <li>• Detect potential sterilization failures from incorrect packaging, load, or malfunctioning equipment and technician errors (e.g., wrong time setting)</li> </ul> Disadvantages: <ul style="list-style-type: none"> <li>• "Pass" response proves item processed but does not necessarily demonstrate sterility</li> <li>• More likely to inaccurately indicate sterilization at marginal cycle parameters (e.g., time)</li> <li>• Does not demonstrate the lethality or killing power of the cycle</li> <li>• Records/indicators must be retained for time period compliant with standards (e.g., 3 years)</li> </ul>	
	Type 2 (Bowie-Dick air-removal test): for dynamic air-removal steam sterilizer cycles, performed by running the test in an empty chamber and before the first load of the day	Type 2: each day the sterilizer is used			
	Type 3: monitors exposure to a single sterilization parameter				
	Type 4: monitors multiple parameters (e.g., for vaporized hydrogen peroxide: time, temperature, and hydrogen peroxide)				
	Type 5: monitors critical parameters and sterilant penetration (time, temperature, and steam)				Type 5: inside of pack
	Type 6: reacts to critical process variables for a specific sterilization cycle				

<p>Biological (BI): directly tests sterilization process with bacterial spores known to be the most resistant to sterilization to demonstrate conditions are adequate to achieve sterilization</p>	<p><i>B. atrophaeus</i> spores (10<sup>6</sup>):</p> <ul style="list-style-type: none"> <li>• Used to monitor ETO and dry heat</li> <li>• Incubated at 35-37°C</li> </ul> <p><i>G. stearothermophilus</i> spores (≥10<sup>5</sup>):</p> <ul style="list-style-type: none"> <li>• Used to monitor steam sterilization, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, and hydrogen peroxide plus ozone</li> <li>• Incubated at 55-60°C</li> <li>• Sensitivity of rapid-readout tests for steam sterilization (1 hour for 132°C gravity sterilizers, 3 hours for 121°C gravity, 132°C vacuum sterilizers) parallels that of the conventional sterilization-specific biological indicators<sup>7-9</sup> and reliably predict 24- and 48-hour and 7-day growth<sup>10</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Steam sterilization: at least weekly with appropriate commercial preparation of spores; preferably each day the sterilizer is used</li> <li>• LTS: (hydrogen peroxide gas plasma, vaporized hydrogen peroxide, hydrogen peroxide with ozone [no longer marketed]), every day the sterilizer is used for each cycle type (e.g., lumened, non-lumened), preferably with each load<sup>6,11</sup></li> </ul>		<p>Advantages:</p> <ul style="list-style-type: none"> <li>• Most experts recognize BIs as ideal because it is the only indicator that directly measures the lethality of the sterilization process<sup>12</sup></li> <li>• Uses standardized, viable population of bacterial spores</li> <li>• Rapid-readout BI (uses enzyme, fluorescence) provide positive results soon after cycle (e.g., ≥15 minutes)</li> <li>• Self-contained BI not subject to exogenous contamination</li> <li>• Provides positive results only when the sterilization parameters (e.g., time and temperature) are inadequate to kill microbial contaminants</li> </ul> <p>Disadvantages:</p> <ul style="list-style-type: none"> <li>• More expensive</li> <li>• Must use spore most resistant to the sterilizing agent (may be affected by availability of spore types)</li> <li>• Requires a separate incubator for incubation at optimal growth temperature (e.g., 35°C, 55°C)</li> <li>• False-positive (e.g., external contamination) BI may occur but are uncommon with self-contained BI</li> <li>• Sterilization records must be retained for a time period compliant with standards (e.g., 3 years)</li> </ul>
--	---	--	--	---

# Table 7. Causes of failure in sterilization and HLD, suggested interventions, and best practices

See recommendation 44, Shenoy et al, 2025 SHEA Expert Guidance: Multisociety Guidance for Sterilization and High-level Disinfection

Factors		Common Failures	Suggested Interventions
<b>Environment</b>			
Physical layout	Dirty to clean flow and separation of dirty and clean <sup>13</sup>	<ul style="list-style-type: none"> <li>• Crossover of dirty over clean supplies needed to clean instruments located in the area designated as “clean”</li> <li>• Pass through window kept open</li> <li>• Doors to the decontamination room kept open</li> <li>• Soiled instruments delivered to clean space</li> <li>• Packaged instruments awaiting sterilization in decontamination space</li> </ul>	<ul style="list-style-type: none"> <li>• Standardize workflow practice and monitor.</li> <li>• Design work area to provide all supplies where and when required</li> <li>• Refer to local building code to separate clean from contaminated. Keep doors, internal pass-throughs, and windows closed when not in use.</li> </ul>
	Supplies and equipment availability and positioning to support the process, including personal protective equipment (PPE)	<ul style="list-style-type: none"> <li>• Ultrasonic cleaner not available when required by MIFU for items being processed</li> <li>• Correct size and type of brushes not available (e.g., for lumened devices)</li> <li>• Ultrasonic cleaner placed in drying area</li> <li>• Inadequate space to perform tasks or place necessary equipment, resulting in worktables too small or need for staff to store regularly needed equipment between uses</li> </ul>	<ul style="list-style-type: none"> <li>• Review device MIFUs to ensure all necessary supplies and equipment are available</li> <li>• Ensure sterile processing expert consultation to ensure compatible supplies and equipment during instrument selection process</li> <li>• Locate equipment and supplies to support unidirectional workflow when processing</li> <li>• Provide adequately sized work area to support all steps in process without needing to reconfigure workspace between tasks and peak workload. (Note: Space challenges can sometimes be addressed by considering staffing patterns)</li> </ul>
	Inadequate lighting	<ul style="list-style-type: none"> <li>• Inadequate lighting impedes cleaning and inspection process</li> </ul>	<ul style="list-style-type: none"> <li>• Follow building code requirements for lighting and consider magnifiers with supplemental lighting</li> </ul>
Airflow, humidity, and temperature	Heating, ventilation, and air conditioning (HVAC)	<ul style="list-style-type: none"> <li>• Failure to maintain positive airflow in clean areas and negative airflow in contaminated areas</li> <li>• Sustained excessive humidity resulting in compromised integrity of sterile packs</li> <li>• Insufficient cooling for staff required to wear recommended PPE, resulting in noncompliance</li> </ul>	<ul style="list-style-type: none"> <li>• Maintain HVAC parameters within specifications provided in ASHRAE 170</li> <li>• Consider providing personal cooling devices for staff (Note: personal fans are not allowed as they may disrupt air flow or create aerosols)</li> </ul>
<b>Organization</b>			
Work assignments		<ul style="list-style-type: none"> <li>• Inadequate time to process medical devices</li> <li>• Items held for reprocessing allowed to dry</li> <li>• Use of staff is not optimized (e.g. Each item processed as it is received vs batching)</li> </ul>	<ul style="list-style-type: none"> <li>• Provide adequate inventory of medical devices for cases, average processing time and availability when scheduling cases</li> <li>• Use compatible products to prevent soil from drying</li> </ul>

	<ul style="list-style-type: none"> <li>• Unpredictable receipt of items requiring processing, resulting in inadequate processing equipment to timely process the items</li> </ul>	<ul style="list-style-type: none"> <li>• Consider individual vs batched device processes to improve efficiencies and prevent soil from drying</li> <li>• Consider staffing at peak workload time periods</li> </ul>
Processes for receipt of instruments	<ul style="list-style-type: none"> <li>• Loaned instruments received</li> <li>• Multiple case carts delivered to the decontamination room</li> <li>• Numerous case carts or medical devices delivered to the decontamination room</li> </ul>	<ul style="list-style-type: none"> <li>• Sterile Processing should have an enforceable process for receipt of loaned instruments including notification of scheduled receipt, delivery with MIFU, specific cut-off time, process for emergency cases</li> <li>• Provide real-time schedule board to sterile processing</li> <li>• Match Sterile Processing staffing to peak processing times</li> </ul>
Inspection not consistently performed	<ul style="list-style-type: none"> <li>• Time, equipment, and expertise not available</li> </ul>	<ul style="list-style-type: none"> <li>• Review the MIFU for inspection instructions, purchase required testing equipment and have staff trained for use</li> <li>• Periodically pull instruments for quality control of inspection process</li> <li>• Create a process to incentivize staff to find instruments that are not appropriate for use (e.g., broken, damaged) or sterilization (e.g., peeling tape)</li> <li>• Make magnifying glass available to aid in inspection of instruments</li> </ul>
<b>Individual factors</b>		
Ability to focus	<ul style="list-style-type: none"> <li>• Noise, distractions, or loud equipment operation</li> <li>•</li> </ul>	<ul style="list-style-type: none"> <li>• Monitor noise level and provide ear protection if warranted by noise level per <a href="#">OSHA</a></li> <li>• Limit distractions and interruptions</li> </ul>
Ergonomics (e.g. counter and sink height, PPE)	<ul style="list-style-type: none"> <li>• Sinks too deep, resulting in poor mechanics that lead to occupational injuries</li> <li>• Eye protection leads to vision distortion, resulting in sharps injury</li> <li>• Oversize gloves interfere with staff performing tasks.</li> <li>• Fatigue caused from prolonged standing</li> </ul>	<ul style="list-style-type: none"> <li>• Install ergonomic equipment sinks and worktables</li> <li>• Make PPE available in appropriate sizes and types</li> <li>• Include staff input in selection of PPE</li> <li>• Consider decontamination staffing patterns to ensure appropriate breaks and relief</li> <li>• Install anti-fatigue mats and provide chairs where possible or appropriate</li> </ul>
Inadequate training	<ul style="list-style-type: none"> <li>• New items brought into the facility without notice or training for Sterile Processing staff</li> </ul>	<ul style="list-style-type: none"> <li>• Consult a representative from Sterile Processing before the purchase of medical devices to ascertain if the staff have the competency, equipment, and time to process the items</li> </ul>
Wide range of medical devices to process	<ul style="list-style-type: none"> <li>• Multiple types of flexible endoscopes models</li> <li>• Multiple types of loaned instrument sets</li> <li>• Instrumentation from all surgical services sent to SP for processing</li> <li>• Instrumentation for the entire hospital sent to SP</li> </ul>	<ul style="list-style-type: none"> <li>• Provide training, MIFUs and time to process medical devices</li> <li>• Device-specific training and reminders</li> <li>• Consider training by device specialty or instrument grouping</li> </ul>

PPE—personal protective equipment; HVAC—heating, ventilation, and air conditioning; MIFU—manufacturer’s instructions for use

## Table 8. Future Considerations

In reviewing the literature, the authors identified knowledge gaps that if addressed could meaningfully impact future approaches to sterilization and HLD.

- 1 What are the risks of contamination and post-procedure infection relative to the time between use and processing?
- 2 To what extent does initial point-of-use treatment mitigate risk?
- 3 What is the risk of contamination and post-procedure infection associated with reusable endoscope accessories, such as biopsy port caps, valves, and forceps?
- 4 What is the risk of contamination and post-procedure infection relative to the methods and duration of storage for lumened endoscopes?
- 5 What are the optimal times and pressures required to adequately dry lumened devices after HLD?
- 6 After HLD, are automated drying systems more effective and efficient than manually drying lumened devices?
- 7 Can a validated method to monitor effective endoscope cleaning be established with thresholds that establish post-procedure infection risk?
- 8 What methods can be validated to ensure sterilization or HLD of 3D devices made by healthcare facilities?
- 9 What is the risk of post-procedure infection due to the type of water used for point-of-care cleaning, processing, and the washer disinfectant?
- 10 What is the risk of post-procedure infection attributable to the type of lubricating agents used with endoscopes?
- 11 What are the ideal cleaning solutions to remove residue on endoscopes due to use of non-water-soluble lubricants?
- 12 Which findings identified during a borescopic evaluation of an endoscope are associated with a higher risk of post-procedure infection?
- 13 What are the optimal methods to ensure that HCP involved in sterilization and HLD are adequately trained?
- 14 To maintain competency, what is the optimal frequency for retraining HCP who are involved in sterilization and HLD?
- 15 How can the process of MIFU development and FDA clearance be improved to ensure the requirements are evidenced-based, clearly written, and practical, and that clarifications and updates are effectively communicated to all interested parties?

## References

1. Bloodborne pathogens: Appendix A. 29 CFR 1910.1030 (1992). <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030>
2. US Food and Drug Administration. Recognized Consensus Standards: Medical Devices. AAMI ANSI ST108:2023: Water for the processing of medical devices 2023.
3. Information about Automated Endoscope Reprocessors (AERs) and FDA's Evaluation (2021).
4. Food and Drug Administration. Definitions. 21 CFR §820.3(z) and 3(aa) (2023). <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/subpart-A/section-820.3>
5. Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee (HICPAC). CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>
6. AAMI. Flexible and semi-rigid endoscope processing in health care facilities. 2023. <https://www.aami.org/st91>
7. Rutala WA, Gergen MF, Weber DJ. Evaluation of a rapid readout biological indicator for flash sterilization with three biological indicators and three chemical indicators. *Infect Control Hosp Epidemiol*. Jul 1993;14(7):390-4. doi:10.1086/646767
8. Vesley D, Langholz AC, Rohlfing SR, Foltz WE. Fluorimetric Detection of a *Bacillus stearothermophilus* Spore-Bound Enzyme, alpha-d-Glucosidase, for Rapid Indication of Flash Sterilization Failure. *Appl Environ Microbiol*. Feb 1992;58(2):717-9. doi:10.1128/aem.58.2.717-719.1992
9. Rutala WA, Jones SM, Weber DJ. Comparison of a rapid readout biological indicator for steam sterilization with four conventional biological indicators and five chemical indicators. *Infect Control Hosp Epidemiol*. Jul 1996;17(7):423-8. doi:10.1086/647333
10. Alfa MJ, Olson N, DeGagne P, Jackson M. Evaluation of rapid readout biological indicators for 132 degrees C gravity and 132 degrees C vacuum-assisted steam sterilization cycles using a new automated fluorescent reader. *Infect Control Hosp Epidemiol*. Jul 2002;23(7):388-92. doi:10.1086/502071
11. AORN. Guideline Summary: Processing Flexible Endoscopes. *AORN journal*. Sep 2016;104(3):237-42. doi:10.1016/j.aorn.2016.06.004
12. Hao H, Li ZX, Ying Z, et al. Study of related factors about positive biological monitoring of steam sterilization and emergent treatment. *Biomedical Research-tokyo*. 2018;29:142-145.
13. CDC. Standard Precautions for All Patient Care. Accessed August 25, 2020, <https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html>