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SHEA

SHEA Expert Guidance

Multisociety guidance for sterilization and high-level disinfection

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Abstract

SHEA, in partnership with ASGE, APIC, AAMI, AORN, HSPA, IDSA, SGNA, and The Joint Commission, developed this multisociety infection prevention guidance document for individuals and organizations that engage in sterilization or high-level disinfection (HLD). This document follows the *CDC Guideline for Disinfection and Sterilization in Healthcare Facilities*. This guidance is based on a synthesis of published scientific evidence, theoretical rationale, current practices, practical considerations, writing group consensus, and consideration of potential harm when applicable. The supplementary material includes a summary of recommendations. The guidance provides an overview of the Spaulding Classification and considerations around manufacturers' instructions for use (MIFUs). Its recommendations address: point-of-use treatment prior to sterilization or HLD, preparation of reusable medical devices at the location of processing, sterilization, and immediate use steam sterilization (IUSS), HLD of lumened and non-lumened devices, processing of reusable medical devices used with lubricating or defoaming agents, monitoring for effectiveness of processing, handling of devices after HLD, augments and alternatives to HLD, processing of investigational devices, tracking of reusable medical devices, and approaches to implementation.

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Intended use

This document was developed following the process outlined in the 2017 "Handbook for SHEA-Sponsored Guidelines and Expert Guidance Documents"[1] and is based on a synthesis of published scientific evidence, theoretical rationale, current practices, practical considerations, writing group consensus, and consideration of potential harm when applicable. The supplementary material includes a summary of recommendations (see *Supplementary Material, Table 1*). Persons interested in previous disinfection and sterilization guidance may view *Centers for Disease Control and Prevention (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities* published in 2008, with updates in 2024.[2] This document contains a "Summary of Major Changes" that summarizes the major differences in these documents (see Table 1).

No guideline or expert guidance document can anticipate all clinical situations, and this document is not meant to be a substitute for individual judgment by qualified professionals.

Methods

This document follows the process outlined in the "Handbook for SHEA-Sponsored Guidelines and Expert Guidance Documents."[1]

The topic was among those proposed and selected by the SHEA Guidelines Committee. The subsequent manuscript proposal developed by the GLC was approved by the SHEA Publications Committee and the SHEA Board of Trustees.

SHEA undertook development of this guidance document to provide current recommendations, following the widely used and cited *Centers for Disease Control and Prevention (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities* published in 2008 with updates in 2024.[2]

This document has been formatted for ease of use, focusing on practices that individuals and organizations who engage in sterilization or high-level disinfection (HLD) should implement.

For terminology and definitions, see *Supplementary Material Table 2*.

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Scope

This guidance document focuses on sterilization and HLD for healthcare facilities, including all locations where healthcare is delivered. Topics that authors determined were out of scope for this guidance are listed in *Supplementary Material Table 3*.

Literature review

The writing panel organized the document around several themes and within those developed questions that were used in the development of search terms (medical subject heading [MeSH] and text word) by two consultant medical librarians (see *Acknowledgements*). Both the questions and search terms were voted on by the panel until unanimous approval was achieved. The medical librarian (JW) developed a comprehensive search strategy for PubMed, Embase, and Cochrane (January 2012 to December 2019, December 19 to September 2020, and September 2020 to June 2021, updated a third time in January 2024 with the same search strategies adjusted by date), restricted to English language articles on human subjects. Article abstracts were screened by two panel members each (blinded) using the abstract management software Covidence (Melbourne, Australia). Abstracts accepted by both reviewers were reviewed as full text. When there was disagreement among reviewers' decisions to include or exclude an abstract, they were adjudicated by the lead authors (ESS and DJW). The period during which articles were collected was from January 2012 to January 2024. Author subgroups reviewed and extracted full text articles remaining after the abstract screening using a standardized form. See *Supplementary Material Table 4* for the literature review criteria, search strategies, and PRISMA.

Consensus

SHEA guidance documents are developed with a formalized process for reaching consensus. Consensus on recommendations and rationale is determined during anonymous comment and voting using a form created in Alchemer (Alchemer Survey, Louisville, CO). If an author had a conflict with a recommendation, they recused themselves from voting on that recommendation (see *Competing interests, COI statement*). For this document's recommendations, unanimous consensus was achieved, with recusals from two authors for recommendations 20, 21, and 34 (see *Competing interests, COI statement*).

Authors

The authors include current and past members of the Society for Healthcare Epidemiology of America (SHEA) Guidelines Committee, as well as members of the American Society for Gastrointestinal Endoscopy (ASGE), the Association for Professionals in Infection Control and Epidemiology (APIC), the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), the Healthcare Sterile Processing Association (HSPA), the Infectious Diseases Society of America (IDSA), the Society of Gastroenterology Nurses and Associates (SGNA), and The Joint Commission.

Audrey Calderwood served as author and representative for ASGE; Kathleen McMullen served as author and representative for APIC; Erin Kyle and Amber Wood served as authors and representatives for AORN; Susan Klacik served as author and representative for HSPA; Laraine Washer served as author and representative for IDSA; Michelle Day served as author and representative for SGNA. All authors served as volunteers.

Review

The document was approved by the authors (see **Consensus**). It was reviewed by the SHEA Guidelines Committee, the SHEA Board of Trustees, ASGE, APIC, AAMI, AORN, HSPA, IDSA, SGNA, and The Joint Commission and endorsed by SHEA, APIC, ASGE, SGNA, and IDSA.

Section 1: Rationale and statements of concern

Burden of outcomes associated with contamination of reusable medical devices

Failure to effectively sterilize or to high-level disinfect equipment can lead to direct transmission of pathogens to patients through contact with contaminated reusable medical devices.[5] Multiple studies in many countries have documented failure to comply with established guidelines for sterilization and disinfection,[6,7] as well as transmission and outbreaks in the setting of no known breaches in processing, highlighting the complexity of devices as a barrier to cleaning and disinfection.[8,9]

Understanding the true burden of pathogen transmission associated with failures in sterilization and high-level disinfection (HLD) is complicated by the lack of recognition that transmission has occurred in settings of colonization or in the latency period between colonization and infection. As a consequence, most transmissions go undetected. If patients progress to infection, the complexity, and resources required to investigate suspected transmission events, lack of standardized surveillance, and publication bias further limit estimates of the magnitude of failures in sterilization and HLD.

For a subset of devices (eg, endoscopic, robotic, flexible reamers, complex orthopedic instruments), specific design features, and limited processing and sterilization options (eg, heat sensitive devices) have been associated with increased risk of processing failure and transmission of infectious agents. Microbial contamination of gastrointestinal endoscopes following HLD or storage has been documented, including contamination with epidemiologically important pathogens such as *Pseudomonas spp, K. pneumoniae, E. coli, Enterobacter spp, E. faecalis,* and *E. faecium*.[10]

Due to the risk of failures in sterilization and HLD, optimal physical design of processing areas (eg, space, layout, ventilation, pressurization), availability of compatible equipment and supplies, training and competency assessment of healthcare personnel (HCP) involved in processing, and competent and engaged leadership oversight are critical to mitigate risks. Sterilization and HLD programs rely on close collaboration among HCP and programs including clinicians, infection prevention and control, sterile processing departments, clinical departments, facility leadership, biomedical engineering, environmental health and safety, supply chain experts, and adequate prioritization and allocation of resources. Facilities without appropriate expertise and resources are not able to implement sterilization and HLD safely and effectively.

Section 2: Background on the prevention of contamination of reusable medical devices

Spaulding classification scheme

More than 50 years ago, Earle H. Spaulding devised an approach to sterilization and disinfection of patient-care items and reusable medical devices.[11] This classification scheme has been retained, refined, and successfully used. Spaulding divided patient

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Table 1. Summary of major changes from the *CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*[3]

Topic	New or revised?	Location (recommendation)
Use of the methods outlined in "Handbook for SHEA Sponsored Guidelines and Expert Documents"	New	Methods
How to use and interpret manufacturers' instructions for use (MIFUs)	New	Section 2: Background on the prevention of contamination of reusable medical devices, Manufacturers' instructions for use
How to perform point-of-use treatment for reusable medical devices	New	Prior to sterilization or HLD
When and how to assess effectiveness of sterilization and high-level disinfection (HLD) of reusable medical devices	Revised	Sterilization (14) Special considerations for HLD (29, 30)
Factors to consider when evaluating a sterilization method for a new device or when switching from one sterilization process to another	New	Sterilization (13)
Considerations for sterilization and HLD of critical or semi-critical investigational reusable medical devices	New	Investigational devices (37)
Considerations for sterilization and HLD of 3D-printed devices or implants	New	Investigational devices (38)
When semi-critical devices or their components or may not need to be high-level disinfected	New	High-level disinfection (19, 20)
How to process ultrasound probes used on intact skin	New	High-level disinfection (21)
Considerations for sterilization and HLD of reusable medical devices used with lubricating or defoaming agents	New	Special considerations for HLD (26)
Storage considerations after reusable medical devices have undergone sterilization or HLD	New	Handling reusable medical devices after HLD (31, 32)
When to use sterile, single use components, accessories, or devices	New	Augments and alternatives to HLD (34-36)
Implementation considerations related to sterilization and HLD processing of reusable medical devices	New	Approaches to implementation (42-45)
Rutala et al. 2008, Table 1. Methods of sterilization and disinfection.[3] Readers may refer to Rutala et al. 2023 for a summary of methods for sterilization and HLD that are legally marketed per the US Food and Drug Administration (FDA) and their advantages and disadvantages.[4]	Not included	

Note: For the purposes of this document, the authors use "legally marketed per FDA" to describe medical devices that have received marketing authorization in the US by FDA, rather than "FDA cleared" or "FDA approved," which denote specific levels of evaluation that vary among the devices referred to in this document. Readers interested to know more about a device's level of FDA evaluation should review its MIFU.

care items and reusable medical devices into 3 categories based on the degree of risk of transmission involved in the use of the items:

1. **Critical**: reusable medical devices that enter sterile tissue or body cavities, or that have contact with the vascular system; items should be sterilized between patients
2. **Semi-critical**: reusable medical devices that encounter mucous membranes or non-intact skin; items should be sterilized or high-level disinfected
3. **Non-critical**: reusable medical devices that encounter intact skin; items should be low-level disinfected

See *Supplementary Material Table 5* for methods for sterilization and HLD of reusable medical devices.

Manufacturers' instructions for use

The US Food and Drug Administration (FDA) reviews medical devices for safety and efficacy before they are allowed to be legally marketed in the United States. Such reviews include but are not limited to assessment of device performance, materials compatibility, and labeling. Labeling includes validated cleaning and sterilization or HLD instructions and indicates that processing of a reusable medical device makes the device safe for subsequent use on patients.

In compliance with FDA's labeling requirements, manufacturers of medical devices provide specific instructions for cleaning, sterilization, or disinfection. Manufacturers' instructions for use (MIFUs) include the steps required for cleaning, sterilization, or the appropriate level of disinfection (HLD or low-level disinfection), the frequency of processing, the products that are compatible for use on the reusable medical device, and other management requirements. Healthcare facilities are expected to follow MIFUs to ensure the safety of care delivered with medical devices. This guidance document is written with the expectation that healthcare facilities are following MIFUs. Prior to purchasing any devices or accessories, a healthcare facility should evaluate whether they have the equipment, materials, physical space, resources, and expertise to meet the MIFU.

The Joint Commission provides a "hierarchical approach" for compliance with infection prevention and control requirements. In descending order:

1. Rules and regulations (eg, FDA, US Environmental Protection Agency (EPA), US Occupational Safety and Health Administration [OSHA])
2. Centers for Medicare & Medicaid Services requirements
3. MIFUs
4. Evidence-based guidelines and national standards

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5. Consensus documents
6. Organizations' infection control processes, policies, and procedures.[12]

Although this document emphasizes adherence to MIFUs, the authors recognize that healthcare facilities are likely to experience challenges in implementation. These may include discrepancies in devices and accessories' MIFUs, inclusion of specific consumables within MIFUs, ambiguous language, and technical barriers. In a survey of infection preventionists (IPs) conducted by APIC, 84% of respondents reported needing to contact a manufacturer for clarification of an MIFU, of which 36% did not receive documentation that addressed their concerns. In this same survey, 42% of respondents reported having been cited by a surveyor for failure to follow an MIFU.[13]

To attempt to resolve challenges in implementing an MIFU, facilities may follow the steps outlined below. Facilities should keep records of all communications with manufacturers and others when clarifying MIFU requirements. It is important to note that facility-specific interactions with a manufacturer can result in variations in practice due to individualized recommendations outside of the published MIFU. These variations may impose additional costs on the facility if they have not been vetted by FDA and may not be based on scientific studies.

1. **When facing a conflict between the reusable medical device's MIFU and the accessory used for processing** (eg, detergent, disinfectant, sterilization container, sterilizer), the *device* drives the process; however, it is important to note that the healthcare facility is responsible for addressing the conflict by first contacting the technical services of the manufacturer of the medical device or accessory. The inquiry may be referred out to the FDA Division of Industry and Consumer Education (DICE) or the Manufacturer and User Facility Device Experience (MAUDE) database.
2. **If the manufacturer of a device did not validate the process, but the manufacturer of the accessory specifically validates its process for that device (or vice versa)**, the process is acceptable. For example, if a device manufacturer does not provide low temperature sterilization parameters, but a low temperature sterilizer provides validated parameters by manufacturer and model for that medical device, then that process is valid. For example, if an endoscope manufacturer does not identify an automated endoscope reprocessor (AER) as compatible, but the AER's MIFU lists the specific endoscope manufacturer's model(s) as compatible with the AER, the process is valid. If neither manufacturer can validate the process, the process cannot be used.
3. **If the MIFU refers to consumable products (eg, detergents, brushes) by name or with general attributes** (eg, neutral pH, contains or does not contain alcohol), and:
   a. A facility does not want or cannot use the specified product, it should contact the device manufacturer to identify the risks of not using the specified product, and whether the manufacturer recommends or expressly prohibits alternative product(s) based on validation activities, scientifically valid justification, or both.
   b. If the manufacturer does not prohibit the alternative product and confirms the product will not create a health or safety risk, the facility may consider using the alternative product. Ideally, the facility would obtain in writing from the manufacturer confirmation that the product will not create a health or safety risk.
4. **If the MIFU contains ambiguous language,** facilities should contact the manufacturer to clarify the MIFU. For example, while facilities may interpret terms such as "should" or "may" in the MIFU as optional, the manufacturer may consider these terms as establishing a requirement.
5. **If the MIFU uses terms without providing the definitions or sufficient detail to allow for implementation** (eg, location of point-of-use cleaning or treatment), facilities should contact the manufacturer to obtain the required details.
6. **If the MIFU is unclear or so complex that it cannot be implemented**, the facility should contact the manufacturer of the device for alternative instructions. If unsuccessful after successive attempts to obtain clarity, the facility may consider contacting DICE.
7. **If the MIFU is not available,** eg, if a device is no longer being manufactured or if a device or is 3D printed (see *38* for recommendations related to processing 3D-printed devices), the facility may consider contacting DICE. If no MIFU is available after contacting DICE, a facility may contact FDA for guidance on meeting current regulations to validate a cleaning and sterilization or disinfection protocol independently that would not affect the functionality of the device. The authors acknowledge that most healthcare facilities are not resourced to be able to do this.
8. **If a facility is technically not able to implement the MIFU**:
   a. Because the MIFU requires adjunctive products not available to the facility (eg, sterilization with a chemical not available to the facility, such as ethylene oxide), the facility should seek an alternate process that is validated by the medical device, alternative equipment, or product manufacturer.
   b. Because the MIFU requires use of a product that is not available (eg, the MIFU instructs not to use alcohol-containing disinfectant, but the facility only has alcohol-containing products), the facility should seek an alternate process that is validated by the medical device, alternative equipment, or product manufacturer.
9. **If the facility cannot implement the MIFU due to irresolvable challenges and it has no further options for recourse**, the facility will need to consider the safety, legal, and regulatory risks of noncompliance with an MIFU.

Section 3: Recommended strategies for sterilization and high-level disinfection

These recommendations frequently state to follow the manufacturer's instructions for use (MIFUs), but for conciseness they do not each describe potential challenges in implementing MIFUs or paths to resolution. Instead, users of this document should refer to the section above (see *Section 2: Manufacturers' instructions for use*).

Prior to sterilization or high-level disinfection

Point-of-use treatment

1. What is the optimal timing and location for point-of-use treatment?

Recommendation:

1. Apply point-of-use treatment promptly to initiate the cleaning process and/or to prevent soils from drying on the reusable medical device.

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2. Perform point-of-use treatment in accordance with the MIFUs for the cleaning product and the medical device.

2. What are the most effective means of treating a reusable medical device prior to transport to the location where sterilization or high-level disinfection (HLD) will be performed?

Recommendation:

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.
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 (eg, blood, silicone). Do not use products known to be fixatives (eg, alcohol) for point-of-use treatment.
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.

3. What is the recommended response to delays in the start of point-of-use treatment?

Recommendation:

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 steps described in *Section 2: Manufacturers' instructions for use*.
2. Keep reusable medical devices moist between use and the start of treatment to prevent soils from drying, unless prohibited by the MIFU.

Rationale 1-3: Prompt point-of-use treatment of reusable medical devices following their use is important to reduce excess contamination before proceeding with the steps of sterilization or HLD. Although the ideal agent for biofilm disruption has not been established, enzymatic detergents, which are commonly recommended as part of a point-of-use treatment, have been shown to be effective at eliminating organic materials and for preparing reusable medical devices for processing.[14–18]

Outbreaks have been linked to delays in processing of high-level disinfected reusable medical devices.[19–22] In a study of stainless steel surgical instruments, the bacterial load began to increase after 6 hours.[23] Biofilms have been demonstrated in vitro to lead to reduced susceptibility to commonly used high-level disinfectants.[24] A study found that a 96-hour *P. aeruginosa* biofilm survived a 5-minute treatment with 2,000 ppm of peracetic acid and was resistant to >4,000 ppm of peracetic acid.[25,26] Experiments have demonstrated that delays in point-of-use treatment and manual cleaning can lead to retained biodebris and contamination, but repeated cleaning effectively can reduce the microbial load on reusable medical devices.[22,27]

Current studies have not compared the efficacy of moisture retention bags, non-drying sprays, gels, or containers.

4. What modifications in point-of-use treatment are required for lumened devices?

Recommendation:

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.
2. Do not modify or adapt cleaning instructions intended for non-lumened devices for use on lumened devices.

Rationale: Most lumened devices are complex in nature with geometries and surface features that limit or prohibit practices that are common to many cleaning methods (ie, they cannot be directly visualized during cleaning) and present enhanced cleaning challenges (eg, biofilm accumulation) compared with non-lumened medical devices. A device's MIFU provides the validated cleaning method and instructions for proper application to ensure adequate cleaning of each device.

5. What are the requirements for transporting contaminated critical or semi-critical devices within the facility to the location of processing?

Recommendation:

1. Package or contain the reusable medical devices in accordance with OSHA requirements.[28]
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.
3. Use a closed, rigid container or closable, fluid-resistant bag to transport contaminated devices.

Rationale: Critical and semi-critical devices that are contaminated with patients' secretions and body fluids pose a risk to HCP[29] and should be handled according to OSHA standards.[28] Point-of-use treatment does not disinfect equipment adequately to eliminate exposure risk.[30] OSHA standards and organizational guidelines recommend dedicated carrying containers that are clearly labeled as contaminated, are leak and puncture-resistant, and are cleanable.[29]

Damage to endoscopic equipment most often occurs during transport.[31,32] Damaged equipment can increase the risk of biofilm formation and processing failure, thereby increasing the risk of transmission of infection.[33–35] During transport, facilities should continue to follow recommendations for preventing exogenous contamination of processed equipment. Container material and ambient temperature, pressure, and humidity all affect the likelihood of contamination,[36–38] although at least one study demonstrated that humidity alone does not affect the likelihood of contamination.[39]

6. What packaging-specific issues are relevant for transport outside of the facility to the location of processing?

Recommendation:

1. Apply the same principles to transport outside of the facility as transport inside the facility. Transport items 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.
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.
3. Follow applicable state and federal regulatory requirements related to transport.

Rationale: Similar packaging considerations apply to transport within a facility as transport outside a facility, with some exceptions.[31] Point-of-use treatment is an even more important practice when transporting a device outside the facility for

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processing, as the total time is increased.[29,40] Increased time can lead to drying of the device, which will make effective processing of it more difficult.[38,41] Additionally, because point-of-use treatment does not disinfect equipment,[30] care must be taken to prevent exposure to those who handle a device during transport.[28] Temperature extremes and damage to devices can occur during transport, and facilities may need to account for extra time to examine equipment for damage after transport.[31]

Preparation at the location of processing

7. Which method(s) should facilities use to clean reusable medical devices at the location of processing?

Recommendation:

1. At the location of processing by sterilization or HLD, follow the reusable medical device's MIFU, including specified steps such as placing it in the open position, disassembling the device and its accessories, actuating it, and cleaning it to remove soils from surfaces.
2. After manual cleaning, if recommended and in accordance with the MIFU, clean reusable medical devices with:

    a. A mechanical washer OR
    b. A mechanical washer with an ultrasonic cleaning phase.

Rationale: Reusable medical devices should be thoroughly cleaned prior to sterilization or HLD. Cleaning reduces the microbial load and removes organic residue that interfere with the sterilization process by acting as a barrier to the sterilization agent or HLD.[42]

HCP should be trained and deemed competent to perform proper cleaning (see *Approaches to implementation*). Poor cleaning may result in residual protein, blood staining, or particles (eg, bone) on the reusable medical device.[43] Successful cleaning occurs when all surfaces are exposed to the cleaning solutions and methods. Design features such as crevices, hinges, and covered surfaces (eg, screw threads covered by thumb screw) of surgical reusable medical devices can shield debris from the forced flow of liquids.[43] One study supported double manual cleaning with specific attention to an internal hinge more effective than double manual cleaning alone.[44] Failure to fully disassemble endoscope accessories prior to sterilization or HLD has been associated with infection transmission events dating back to the 1980s.[45]

Mechanical washers for cleaning are more systematic and reproducible than manual cleaning and can offer additional microbial reduction.[46] Mechanical washers use cleaning solutions and rinsing under pressure to physically remove microorganisms. Mechanical washers are validated and are legally marketed per the FDA by demonstrating effectiveness in thoroughly cleaning medical devices.[43]

Ultrasonic cleaning and thermal inactivation at 150°F to 240°F are sufficient to reduce or eliminate microorganisms, but spores can be more resistant to thermal inactivation.[47,48] Ultrasonic cleaning removes soil and microorganisms by cavitation and implosion, with waves of acoustic energy in aqueous solutions used to disrupt the bonds that hold particulate matter to surfaces.[43] Ultrasonic cleaning should meet the reusable medical device's time and temperature parameters, as specified in the MIFU.

8. Are there any reusable medical devices that should be segregated from others for processing?

Recommendation: 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.

Rationale: From an infection prevention and control (IPC) perspective, facilities do not need to segregate reusable medical devices, except those with known or suspected prion contamination. Prions are out of scope for this document. Readers may review published guidelines specific to prions.[3,49–51]

Facilities may need to segregate certain categories of reusable medical devices from others for non-infection prevention reasons. These reasons include preventing potential damage to delicate reusable medical devices (eg, ocular instruments), patient sensitivity to cleaning solutions and detergents, detergent residues that may contribute to ocular toxic anterior segment syndrome (TASS),[50,51] and for occupational safety (eg, sharps safety).

9. What type of water should be used for rinsing medical devices in a mechanical washer?

Recommendation:

1. Verify that all water supplied to the facility meets the requirements described in the mechanical washer's MIFU.
2. Ensure that the water used in processing is part of the facility's water management plan.

Rationale: Water quality is a principal factor in cleaning and disinfection. Although limited data exist on water quality for rinsing of semi-critical reusable medical devices,[52,53] to avoid damage to the devices being washed and disinfected and to the mechanical washer itself, the water used must have the temperature, pH, and chemical balances, as specified in the MIFU.[54–57] Water must be compatible with the disinfection process[58,59] and must not increase microbial load or leave residual endotoxin above recommended levels specified in the MIFU.[57] These goals can be achieved using treated water (eg, deionized, reverse osmosis, sterile, filtered; see *Supplementary Material Table 2* for terminology and definitions), but no single treatment system will account for all issues and will need to be monitored and modified as needed. Water systems themselves can fail and must undergo regular maintenance and monitoring.[60]

10. What methods should facilities use to verify that mechanical washers are working effectively?

Recommendation:

1. To confirm that mechanical washers adequately perform all stages of the cleaning cycle, perform cleaning verification testing per the equipment's MIFU.
2. Record the results when the equipment is installed, after major repairs, and each day that it is used.
3. Incorporate verification tests for mechanical washers that:

    a. Monitor at the point-of-use
    b. Generate immediate results
    c. Indicate that all stages in the mechanical washer's cleaning cycle meet the mechanical cleaning parameters.

Rationale: Verification methods for mechanical washers confirm that sufficient temperature, wash time, and detergent level was used.[43,46,61,62] Facilities that use commercial cleaning verification tests for mechanical washers should ensure that they are validated by the manufacturer, as the FDA does not independently validate or clear mechanical washer verification tests.

11. Should healthcare facilities test the quality of water used for medical device processing at the point of use?

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Recommendation: 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:

1. When indicated by the MIFU.
2. When recommended by the local or state public health department.
3. In the setting of outbreak investigation when a water source is suspected.
4. When investigating staining, damage, or residue on processed medical devices.

Rationale: While water quality can be variable,[63] existing evidence does not support routine point-of-use testing of water quality to reduce the risk of transmission of infectious pathogens; however, there are exceptions to this, such as to help identify the potential source of contamination when a water source is suspected during an outbreak.[64] Types of water that may be required by the MIFU have been defined.[65]

Several reports have documented instances of contamination of bronchoscopes[66,67] and endoscopes[64] from rinse water that ultimately were determined to represent pseudo-outbreaks. *P. aeruginosa*, *M. abscessus*,[66] *Mycobacterium gordonae*,[67] and *Aspergillus fumigatus*[64] were cultured, but none were clinically significant.

12. What additional methods, if any, are recommended to assess the cleanliness of reusable medical devices prior to sterilization and HLD?

Recommendation:

1. Beyond external visual inspection (see *42*), no recommendation can be made for additional methods for cleaning verification to prevent transmission events.
2. No recommendation can be made for the use of surrogate tests to detect residual organic material (eg, ATP, protein, heme) to assess adequacy of cleaning. Currently, these tests are not correlated with reduction of risk for microbial contamination or transmission.
3. For training purposes, facilities may consider including surrogate tests for medical devices that have a higher incidence of cleaning failure, such as lumened endoscopes.

Rationale: As standard practice, HCP should visually inspect reusable medical devices at various stages: prior to sterilization or HLD, after sterilization or HLD, and before use.

Surrogate tests (eg, ATP, protein, heme) to detect microbial growth cannot be used to assess for effectiveness of either cleaning or HLD for several reasons:[68–70]

- ATP is a gross measure of organic material, and it may detect an organism's residue rather than viable bacteria.
- Despite several studies that have correlated ATP and protein results with culture values,[71–79] specific measures and levels of cleaning effectiveness have not been validated as indicators of infection risk.
- The relationship between ATP and bacterial cultures is non-linear and may result in missing low levels of viable bacterial contamination.

Facilities may use surrogate tests to evaluate training,[62,72,80–84] investigate inadequate cleaning, and assess the impact of education and interventions,[71,81,85–91] but the frequency for using surrogate tests requires more study. If used, the results of surrogate tests should be interpreted according to manufacturer-recommended thresholds.

Sterilization

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?

Recommendation:

1. Ensure the change(s) are permitted by the MIFU.
2. Review the implications of changing methods (eg, effectiveness, materials compatibility, packaging, detergent or sterilant residues, absorption of sterilant by packaging, moisture, rust).

Rationale: Facilities should adhere to the sterilizer's MIFU, which will define how to load the chamber depending on the modality used. Consequently, changing to another sterilization modality may result in less effective microbicidal processing or may adversely affect materials compatibility, resulting in damage to the item or potentially toxic residue. The original equipment manufacturer can conduct the appropriate validation studies that demonstrate the safety and effectiveness of a sterilization modality, including the methods to safely change a sterilization modality.[92]

The facility should contact the original equipment manufacturer to obtain assurance that the device type has been validated for processing with the new modality. Such validation should support a sterility claim (a sterility assurance level of 10^{-6}), assurance of product performance and materials compatibility, and sufficient residue reduction.

14. How should facilities monitor the effectiveness of sterilization?

Recommendation:

1. Monitor sterilizing conditions using a combination of physical, chemical, and biological indicators (see *Supplementary Material Table 6*).
2. At minimum, include physical and chemical indicators for all sterilizations, with regular addition of biological indicators.
3. Always include biological indicators and Type 5 chemical indicators for sterilization of implants.

Rationale: The physical, chemical, and biological indicators need to be specific to the sterilization method (see *Supplementary Material Table 6*) and interpreted in compliance with the MIFU.

Physical indicators should be read daily via examination of the cycle record chart (cycle printout) and relevant indicators (eg, time, temperature, relative humidity, pressure, gas concentration).

Chemical indicators have been grouped into 6 types based on their design and performance attributes (eg, Type 1 process indicators, Type 2 Bowie Dick test).[93] If the internal or external indicator suggests inadequate processing, the reusable medical device should not be used.[94] Chemical indicators are convenient, inexpensive, and indicate that the device has been exposed to the sterilization process; however, in one study, chemical indicators were more likely than biological indicators to inaccurately indicate sterilization at marginal sterilization times.[95] Based on current studies, chemical indicators should be used in conjunction with biological indicators, although they should not replace biological indicators.[95]

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Most experts recognize biological indicators as being closest to the ideal monitors of the sterilization process because they measure the lethality of the sterilization process directly by using resistant microorganisms (eg, *Bacillus* spores), rather than testing the physical and chemical conditions necessary for sterilization.[96] Since the *Bacillus* spores are resistant and present in greater numbers than common microbial contaminants found on patient care equipment, inactivation of these spores in a load strongly implies that other potential pathogens were killed.[97–99] If a sterilizer is used frequently (eg, several loads per day), daily use of biological indicators allows earlier discovery of equipment malfunctions or procedural errors, thereby minimizing the extent of patient surveillance and product recall needed in the event of a processing failure.

Facilities should use biological indicators to monitor the effectiveness of sterilizers at least weekly with a preparation of spores that are legally marketed per FDA (eg, *Geobacillus stearothermophilus* for steam and H_2O_2, BIs with *Bacillus atrophaeus* for ethylene oxide) intended for the type and cycle parameters of the sterilizer. For low-temperature sterilization technologies (eg, hydrogen peroxide gas plasma, vaporized hydrogen peroxide, hydrogen peroxide with ozone), facilities should perform biological indicator monitoring every day that the sterilizer is used for each cycle type (eg, lumen, non-lumen) or as specified by the MIFU.[94] Facilities may choose to run a biological indicator more frequently (eg, daily) so that, in the event of a sterilization failure, there are fewer devices to embargo while the failure is assessed. Facilities should use biological indicators and Type 5 chemical indicators to monitor each load that contains implantable objects. Implantable items should not be used until the biologic indicators' results are negative.[2]

15. What should be done if one or more methods used to monitor the effectiveness of sterilization indicate failure?

Recommendation:

1. If a failure is identified by a biological indicator, immediately retrieve and reprocess all affected devices back to the last negative result.
2. If a failure is identified by a physical or chemical indicator, consider affected reusable medical devices non-sterile and embargo them while the cause of the failure is assessed.
3. Develop processes to investigate root causes of indicator failures.
4. Take a sterilizer out of service during the investigation of a failure.
5. Notify IPC and the areas using them for appropriate management (see *14, 16* and *Supplementary Material Table 7*) if reusable medical devices have been used before the failure was identified.

Rationale: Following a positive biological indicator, facilities should consider all reusable medical devices that have processed in that sterilizer to be non-sterile, dating from the sterilizer's last negative biological indicator to the next cycle showing satisfactory biological indicator results. These non-sterile reusable medical devices should be retrieved, if possible, and reprocessed.[2] The cause of the positive biological indicator should be investigated for improvement. If the investigation indicates the cause of the failure was a malfunction of the sterilizer, the sterilizer should not be used until it has been repaired, and there have been sequential negative biological indicators.[96,100]

16. What steps should a facility take after identifying a processing failure or a potential transmission event?

Recommendation:

1. Immediately remove improperly processed reusable medical devices from use.
2. Cease using any processing equipment suspected of not functioning properly.
3. Follow an organized, timely process using available data to assess the potential infection risk to patients from the processing failure.
4. With the guidance of IPC experts, involve partners, including public health authorities when appropriate, to determine and carry out follow-up actions.
5. Develop and implement preventive strategies based on the lessons learned from the failure in processing or identification of a potential transmission event.

Rationale: Failures of sterilization or HLD processing can lead to outbreaks if not managed properly.[101] Facilities should follow a clear, timely, and logical process for assessing the infection risk to patients.[100,102] Follow-up actions should be determined and carried out by a multidisciplinary team that includes clinicians, processing leaders, IPC, and risk management. Finally, the facility should assess the opportunities for improvement that would prevent future failures in processing or potential transmission events. Risk analyses and quality improvement tools may be useful to prioritize prevention actions.[103–105]

One study reported use of molecular sequencing of newly detected cases after a suspected exposure event, finding that these new cases were not actually linked to the exposure event.[106] Facilities should be aware that increased surveillance after an exposure event may detect new cases that may or may not be linked to the exposure event.

Immediate use steam sterilization

17. Is there a risk to immediate use steam sterilization (IUSS) when properly performed?

Recommendation:

1. Although immediate use steam sterilization (IUSS) is an effective method of sterilization when properly performed, facilities should not routinely use IUSS.
2. Design and implement processes that ensure that when IUSS is used:
    a. IUSS is performed by trained, competent HCP (see *43*) in accordance with the reusable medical device or implant's MIFU
    b. The sterilizer and the device or implant's MIFUs include instructions for IUSS
    c. The device or implant is placed in a container validated for IUSS and legally marketed per FDA for this purpose
    d. The sterilization process is verified to be successful according to the appropriate indicator for the device or implant (see *14* and *Supplementary Material Table 6*)
    e. Measures are taken to prevent contamination of the device or implant during removal from the sterilizer and transfer to the sterile field
    f. Before patient care, the device or implant that was subjected to IUSS is cooled to body temperature without compromising sterility.

Rationale: IUSS is effective when devices or implants are properly cleaned prior to IUSS, appropriate temperature, pressure, and exposure times are met, and adequate drying and cooling occurs. In practice, a higher usage of IUSS can be a result of ineffective

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planning for scheduled or frequently occurring but unscheduled procedures. Although IUSS can produce a sterile medical device, lack of equipment and supplies, and time constraints to process a device that is needed immediately for intraoperative use, can result in pressure on operating room HCP to eliminate or modify one or more steps prior to sterilization, increasing the risk for errors.

HCP who are not trained in the complex nature of processing with IUSS are not equipped to effectively perform the necessary processing steps. Facilities should restrict processing actions to HCP who have demonstrated competency in all the steps involved. Following an MIFU's IUSS instructions is the only way to assure that the processing being used was validated to be effective. This includes the use of containers specified by the MIFU.

Monitoring and audits of HCP can verify that processing steps were performed in accordance with the MIFU, including the monitoring of the IUSS cycle (physical parameters, chemical indicators, biological indicators), and of patient outcomes (eg, intraoperative complications, prolonged procedure time, occurrence of surgical site infections [SSI]).

Limited research exists on the association between the use of IUSS and the incidence of SSI. In one large, retrospective review of more than 70,000 patients undergoing total knee arthroplasty, total hip arthroplasty, laminectomy, or spinal fusion, the increase in risk of SSI reported for patients whose procedures used instrumentation sterilized by IUSS versus non-IUSS was not statistically significant.[107]

HCP should use precautions to prevent burns (eg, transport tray using heat-protective gloves). Patient burns should be prevented by either air-cooling the instruments or immersion in sterile water.[108] A report of 2 patients who received burns during surgery from items that had undergone IUSS reinforces the need to develop policies and educate HCP to prevent the use of medical items hot enough to cause clinical burns.

18. When may IUSS be used?

Recommendation:

1. As a last resort when the standard sterilization process cannot be performed (eg, 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.
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.

Rationale: IUSS may be performed in the event of unexpected unavailability of an implant or reusable medical device for a procedure.[109] This unavailability might be an issue of intra-procedural contamination, an urgent or emergently performed procedure with inadequate time to identify and locate all the needed medical items in advance, or another unforeseen event. IUSS should not be used routinely as an alternative to planned and scheduled procedures.

High-level disinfection

19. How should portions of a semi-critical device that do not come in contact with mucous membranes or non-intact skin (eg, cables, connectors) be cleaned and disinfected?

Recommendation: Clean and low-level disinfect portions of a device that do not come in contact with mucous membranes or non-intact skin (eg, cables, connectors) according to the device's MIFU.

Rationale: Components such as cables and connectors should undergo surface cleaning to remove gross soil and debris and undergo low-level disinfection to decrease microbial contamination. Sterilization or HLD is not required for these portions of devices, as intact skin serves as an effective barrier to transmission.[92]

20. Does a single use sheath or probe cover allow for low-level disinfection instead of HLD?

Recommendation: Sheaths do not eliminate the need for HLD for a semi-critical reusable medical device; unless otherwise specified by the MIFU, HLD is indicated.

Rationale: HLD should be used for processing semi-critical devices even when a sheath is used. While sheaths are expected to reduce the risk of contamination, studies have shown residual contamination. Ultrasound probe covers, including sheaths, can fail due to perforations or probe contamination during cover removal.[110–112] Sheath perforation after transrectal, ultrasound-guided prostate biopsies has been demonstrated in up to 9% of procedures.[113] A systematic review and meta-analysis assessed the prevalence of contamination of endovaginal ultrasound probes following sheath removal and noted an overall bacterial contamination rate of 33.7%.[114]

As an exception, facilities can effectively process semi-critical reusable medical devices using compatible low-level disinfection or intermediate-level disinfectants rather than HLD when a single use sheath that is specifically designed to be compatible with a specific medical device is used in accordance with both the device's and the sheath's MIFUs. This option is acceptable only if the device, with its accompanying MIFU, are legally marketed per FDA for the specific sheath-device combination and the disinfectant is registered with the US Environmental Protection Agency (EPA). In addition, after use, HCP should visually inspect sheaths and endoscopes for moisture and signs that may suggest a non-intact sheath. If a sheath's integrity is breached, the facility should perform sterilization or HLD according to the MIFU.

21. Is sterilization or HLD needed for ultrasound probes used for percutaneous procedures on intact skin (eg, central line placement, paracentesis, biopsy)?

Recommendation:

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.
2. Clean and low-level disinfect these ultrasound probes, following the MIFU.

Rationale: The ultrasound probe is considered a non-critical item by the Spaulding classification, as intact skin serves as an effective barrier to most organisms. After the probe is thoroughly cleaned, a low-level disinfectant that is EPA-approved, compatible with the MIFU, and applied for the contact time required by the disinfectant type eliminates vegetative bacteria and viruses from the surface of the device. There is no documentation of transmission of infectious agents from non-critical items to patients after cleaning and low-level disinfection has been performed correctly.[115,116]

This question does not address disinfection of ultrasound probes that come in contact with non-intact skin. Per the Spaulding classification, items that come in contact with mucous membranes or non-intact skin are considered semi-critical[11].

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22. How should non-lumened devices be stored following HLD?

Recommendation:

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.
2. Store ready-for-use reusable medical devices separate from contaminated (used) devices and ensure they are easily distinguishable (eg, prominently labeled as "patient ready") from those that are not ready for use.

Rationale: Reducing the risk of contamination requires that processed devices be dry, protected from the external environment, and not able to be confused with contaminated items. Devices must be dry prior to storage, as moisture may promote growth of any residual microbes present after HLD or introduced through handling prior to storage.[117] Failure to separate contaminated devices from reprocessed devices may lead to reuse of a non-cleaned or disinfected device with the potential for transmission of pathogens.

High-level disinfection of lumened devices

23. What are the requirements for adequate germicide flow?

Recommendation:

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.
2. Passive flow is insufficient for removal of microorganisms. Positive pressure is required; however, no recommendation can be made for the minimum pressure required.

Rationale: AERs are designed to immerse and flush the lumened reusable medical device and its internal channels with liquid cleaning and disinfecting/sterilizing agents. Most AERs also perform one or more of the following: final water flush, alcohol rinse, and air purge.

When using an AER, facilities should follow the MIFU and confirm proper use of connectors to ensure that germicide and rinse water flow through the device's channels.[118] AERs should be monitored according to their MIFUs to verify ongoing adequacy of cycles.[119] Individual AERs have specific flow and temperature ranges for operation and flow sensors to detect channel obstruction.[41] If an AER cycle is interrupted, sterilization or HLD cannot be ensured and the entire cycle should be repeated. If using manual disinfection, facilities should follow the lumened reusable medical device's MIFU.

24. Is there a preferred drying method following HLD of a lumened device?

Recommendation:

1. Dry exterior surfaces of the lumened reusable medical device according to the specifications in the MIFU (eg, cloth that is clean or sterile, low-linting, or lint-free).
2. Use pressure-regulated instrument air or HEPA-filtered air to dry the device's lumens following HLD for the time specified by the device's MIFU.
3. Always dry a device following HLD, even if it is planned for immediate use.

Rationale: Any moisture remaining on the exterior and interior surfaces of the device can facilitate microbial growth and biofilm formation during storage. Moisture retained in processed flexible endoscopes has been associated with patient infections,[6,120] biofilm growth,[121] microbial contamination,[90,117,122] and increased ATP values.[117,123] Drying should always occur, as residual moisture poses a risk to patients by supporting microbial growth.

Purging lumens with instrument air or HEPA-filtered air facilitates drying and prevents the introduction of contaminants that may be present in lower-quality air. The MIFU may provide guidance on the maximum air pressure that can be used. Air pressure that is too high may damage the internal channels of the endoscope. Some AERs have a cycle to purge rinse water from the endoscope at the end of the processing cycle, but this cycle may not be sufficient to dry the endoscope channels.

Studies have assessed drying times up to 10 minutes for manual and automated drying.[78,117,123–127] In one study, manual drying was associated with significantly more fluid droplets on borescope inspection and higher ATP values at 48 hours and 72 hours after processing, compared with automated drying.

Flushing channels with alcohol, either manually or as part of an AER cycle, may facilitate drying of the endoscope channels and may prevent contamination; however, studies are mixed on whether use of alcohol leads to an increase in drying time or is effective at preventing contamination.[82,85,90,117,122,123,125] Concern also has been raised that alcohol may serve as a fixative, making biofilm more difficult to remove.[125]

25. How should lumened reusable medical devices be stored following HLD?

Recommendation:

1. After HLD, store lumened reusable medical devices and their accessories in accordance with their MIFUs. This includes but may not be limited to:
   a. Completely drying lumened reusable medical devices and accessories (see *24*).
   b. Storing lumened devices and accessories in a manner that protects them from contamination and damage, in accordance with their MIFUs.
   c. Placing lumened devices in the position indicated by their MIFUs (ie, 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.
2. Place storage cabinets in a secure location that protects their contents from contamination and damage.
3. Ensure storage cabinets are kept clean and dry.
4. Adequately maintain storage cabinets per their MIFUs.
5. No recommendation can be made for the use of drying cabinets to prevent the transmission of infections.

Rationale: Lumened devices are more difficult to dry than non-lumened devices. According to their MIFUs, lumened devices should be dried and stored in secure, dedicated cabinets to prevent contamination and damage.

Drying storage cabinets have a system that circulates and forces dry, usually HEPA-filtered air, through the endoscope channels.[128] Several small studies suggested that drying cabinets may reduce the risk of growth of organisms like *Pseudomonas aeruginosa*.[129,130] One study inoculated *Pseudomonas aeruginosa* into colonoscope, enteroscope, and duodenoscope channels and compared bacterial growth rates over time between endoscopes that were stored in

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automated drying and storage cabinets with forced compressed air circulated through channels versus endoscopes that were stored outside the cabinet. This study reported a decline in bacterial growth over time for endoscopes stored in automated drying cabinets compared with increases over time in endoscopes stored in a non-controlled environment.[131]

Some data have suggested that optimizing drying before storage (eg, by using automated drying devices that apply continuous air through all channels for a set period of time) results in minimal potential incremental benefit to using a ventilated storage cabinet.[124] Although drying and ventilating storage cabinets may address challenges related to assessing dryness, there is an absence of clear acceptable levels for dryness. Also, the use of drying cabinets has not been demonstrated to reduce infection risk. Thus, a facility may conduct a risk assessment that considers factors that affect the ability to adequately dry endoscopes prior to storage, the potential benefits of augmented drying options, and resources required to acquire, install, and maintain cabinets to make decisions about the type of storage cabinet(s) for their specific setting.

Special considerations for high-level disinfection

26. When and how should lubricating and defoaming agents be used for medical devices?

Recommendation:

1. Use lubricating or defoaming agents for medical devices when clinically needed and as permitted and specified by the MIFU.
2. Preferentially choose water-soluble agents over non-water-soluble agents, if permitted by the MIFU.
3. Prior to processing, clean the device after use to remove lubricating or defoaming agents in accordance with the MIFU.
4. For lumened, semi-critical reusable medical devices:
    a. Minimize the use of non-water-soluble defoaming agents consistent with the amount clinically needed for a successful completion of the procedure.
    b. When the device is used with simethicone:
        i. Apply the minimum amount of simethicone required for a successful procedure.
        ii. Follow the MIFU for how to add the simethicone to the device.
        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.
        iv. After use, clean the device as specified by the MIFU.

Rationale: Lubricating agents prevent friction that can result in tissue abrasion and prevent corrosion of the medical device, and defoaming agents may be technically necessary for specific procedures (eg, for adequate visualization).

Lubricants and defoaming agents that are not water-soluble are difficult to remove from flexible endoscopes and may not be permitted by the endoscope's MIFU. A multisite study found oily, sticky residue on endoscopes and a mass inside a patient-ready ultrasound endoscope.[132] The researchers reported finding use of cooking oil, silicone sprays, and tissue adhesives during endoscopies, despite the endoscope's MIFU stating to avoid using simethicone, oil, petroleum, or silicone-containing products because they are not water soluble. If oil- or grease-based agents are used, they should be specified as permitted by the MIFU, and facilities should use cleaning agents that are specifically effective in removing them.[133]

Water-soluble alternatives for lubricants (eg, lidocaine jelly) are preferred if they are allowed by the device's MIFU because cleaning does not consistently remove oil- or grease-based agents entirely from reusable medical devices.[134]

Multiple studies have found that simethicone is commonly identified during borescope inspection in patient-ready endoscope channels, appearing as white liquid residue and crystallized white fragments.[85,117,132,135,136] Simethicone use has been associated with retained moisture in processed endoscopes, which can impair drying and may be related to increased ATP values.[85,127,132,135] A study compared different concentrations of simethicone (0.5%, 1%, 3%) to water and performed borescope inspection and ATP testing, finding that medium-to-high concentrations of simethicone were associated with significant increases in ATP values and the number of retained fluid droplets. Simethicone was detected at low concentrations after 2 AER processing cycles in endoscope channels.[127] In contrast, another study that conducted borescope inspections did not find simethicone despite its use at the facility.[137]

One study assessed the effects of varying levels of simethicone concentrations and delivery using an irrigation water bottle versus injection through the working channel. Simethicone concentrations were higher when the solution was added to the irrigation water bottle. When simethicone was added to the working channel rather than the irrigation water bottle, the total volume of simethicone solution needed for procedures was reduced (940 mL vs 180 mL; $P < 0.001$). The investigators found that simethicone was detectable after processing in the working channels, even when used at low concentration.[127]

27. Does HLD inactivate human papilloma virus, multidrug-resistant bacteria, mycobacteria, and multidrug-resistant fungi (eg, *C. auris*)?

Recommendation: HLD, when properly performed, is shown to be effective against human papilloma virus (HPV), multidrug-resistant microbes including multidrug resistant bacteria and fungi (eg, carbapenem-resistant *Enterobacterales, C. auris*). Mycobacteria, however, are relatively resistant to some high-level disinfectants.

Rationale: Although some studies have suggested resistance of HPV to certain high-level disinfectants,[138] ample evidence has shown the effectiveness of a wide range of HLD agents against HPV.[139,140] Methods that are legally marketed per FDA using hypochlorite, peracetic acid, or ortho-phthalaldehyde (OPA) may be used as specified per the device's MIFU for processing.[141] HLD disinfectants have efficacy against vegetative multidrug-resistant bacteria.[142] Similarly, HLD methods that are legally marketed per FDA have been shown to be effective against *C. auris*.[143] Mycobacteria are relatively resistant to glutaraldehyde and OPA;[144,145] however, peracetic acid and hydrogen peroxide effectively kill aldehyde-resistant strains of mycobacteria. An outbreak of *M. abscessus* in a Brazil hospital unit was attributed to cross-contamination and resistance to glutaraldehyde.[66]

28. Is automated processing superior to manual HLD?

Recommendation:

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.
2. Maintain automated processing systems according to their MIFUs.

Rationale: Automated processing has been shown to be either equally effective or superior to optimal manual HLD for a variety of

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reusable medical devices, including lumened endoscopes, solid surgical reusable medical devices, and ultrasound probes.[83,89,124,146–152] Automated processing provides greater reliability, reduced potential for operator errors or inadequate manual cleaning,[146] and reduced exposure of HCP to potentially harmful chemical agents, such as OPA,[153] glutaraldehyde,[154] and others.[155]

Use of automated systems does not completely remove the need for vigilance and human involvement. The systems need to be maintained, as they can have failures that can result in transmission.[156–161] Factors unrelated to automation, such as germicidal agent activity and equipment damage, can influence the quality of HLD by automated processing.[34,35,45,162,163] Finally, no fully automated HLD system currently exists, meaning at least one or more steps involve manual intervention, including visual inspection.[33,83,85,162] Automation with proper monitoring and quality assurance of both the automated and manual steps is likely the safest, most effective approach.[119]

It should be noted that automated and manual HLDs are performed in addition to the initial manual cleaning of devices, and automated cleaning features in AERs are used in addition to manual cleaning, per the device MIFU (see *7*).

29. What should facilities monitor to ensure that HLD conditions are achieved?

Recommendation: Monitor compliance with the MIFU, including the concentration of the active ingredient(s) in a liquid chemical sterilant or high-level disinfectant (ie, the minimum effective concentration (MEC) and minimum recommended concentration [MRC]), temperature, and time.

Rationale: Inadequate concentrations or duration of exposure can lead to residual contamination.[164]

30. Should facilities routinely use microbial cultures to assess the effectiveness of HLD for lumened and non-lumened devices?

Recommendation: No recommendation can be made for routinely using microbial cultures to assess the effectiveness of the HLD process.

Rationale: Although facilities can reliably measure the effectiveness of HLD by culturing reusable medical devices for residual bacterial contamination, routine culturing is resource intensive and there is no evidence to support that routine microbial surveillance reduces risk of transmission events. Facilities that are considering routine culturing will need to balance the cadence of surveillance (eg, after each HLD event, monthly, or after a defined number of uses) with the cost of additional devices to make up for those that are embargoed while awaiting culture results, as well as costs for culturing and HCP.[165,166] Specialized reference laboratories also may be required, as most clinical laboratories are not equipped to process environmental samples. Additionally, variability in culturing techniques affects the tests' sensitivity (eg, sampling solutions, culture media, incubation period, antegrade versus retrograde collection).[165,167–169] Resources exist to help facilities culture scopes, including culturing protocols for duodenoscopes from FDA, CDC, and the American Society for Microbiology (ASM)[170] and preassembled toolkits to facilitate aseptic collection for culturing by a reference laboratory.[90]

Facilities that have implemented routine surveillance culturing of lumened endoscopes after HLD have reported a broad range of positive culture rates from 3% to 35.7%. Skin contaminants were more frequently cultured than enteric organisms.[171–174] In post-market surveillance, researchers cultured high-concern organisms in 6.6% of samples from fixed end-cap design duodenoscopes and in 1.1% of duodenoscopes with single use components.[175]

Facilities may consider culture-based or non-culture-based methods as part of a quality assurance program to detect errors in processing, contamination of AERs, and unsuspected endoscope damage[19,176] (see *12*) or as part of an outbreak investigation where a medical device may be implicated in transmission (see *16*).[177] Although no recommendation is available for routine culturing of endoscopes, if a facility does perform cultures (as part of research, outbreak investigations, or quality assessment) and identifies growth of organisms, actions and mitigation strategies should occur in accordance with the FDA/CDC/ASM guideline,[170] which references the types of pathogens recovered (eg, high concern organisms, low/moderate concern organisms) and the level of growth and provides recommended actions (see *39-41* for tracking of reusable medical devices). Positive endoscope cultures of high-concern organisms per the FDA/CDC/ASM guideline[170] have been associated with transmission and outbreaks. There is no minimum acceptable threshold for the number of high-concern organisms cultured. Positive endoscope cultures after HLD with low- or moderate-concern organisms do not necessarily represent a failure of processing but may be related to recontamination during the storage or culturing process.[170] Microbial limits for low-concern organisms identified through culturing endoscope channels have not been correlated to patient outcomes. Microbial limits depend on culturing methods and techniques that have not been standardized.

Handling reusable medical devices after high-level disinfection

31. After processing, how should reusable medical devices that have undergone HLD be handled for storage?

Recommendation:

1. Follow the MIFU for how to handle reusable medical devices that have undergone HLD and are ready for storage.
2. Perform hand hygiene before handling devices that have undergone HLD.
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.

Rationale: An experimental study using ATP testing found that when HCP performed hand hygiene or donned gloves, the reusable medical devices that were tested had less contamination.[178] There is no evidence to support requiring HCP to don gloves after they have properly performed hand hygiene to reduce the risk of contamination or transmission.

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?

Recommendation:

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 (eg, flood, non-contained construction).

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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.
3. If there is evidence of contamination, repeat HLD, processing the device in accordance with the MIFU.

Rationale: Previous recommended time-based durations of storing lumened reusable medical devices (ie, their "hang time") were varied and was based on limited evidence.[179,180] The existing literature is limited by variability in the storage conditions tested (eg, cabinet, no cabinet), the type of processing (sterilization or HLD), the types of lumened devices studied (eg, duodenoscopes, echoendoscopes, bronchoscopes, gastroscopes, colonoscopes), the duration tested, and where culture samples were gathered (channels or endoscope surfaces), although studies that assessed for contamination at various time points from 2 days to 12 weeks found that lumened reusable medical devices can be safely stored for these durations.[181]

Due to inconclusive evidence to provide a maximum storage interval, several guidelines have recommended that institutions perform a risk assessment to establish their own policies,[94,182,183] using a time- or event-based approach (eg, a breach in storage conditions) for determining when to repeat processing. No evidence has directly addressed the maximum time for storage of non-lumened devices. Facilities should consider the utility of a policy that is based on these factors. For example, a "hang time" policy would be useful for devices that a facility uses infrequently, but such a policy may not be useful for devices that a facility uses often.

Considerations for developing a facility-specific policy should include storage conditions, types of processing, the types of devices used, their frequency of use, wear and tear, available HCP, and cost.

Augments and alternatives to high-level disinfection

33. Is there evidence to support the use of additional cycles of HLD (ie, double HLD or "dHLD") to reduce the risk of residual contamination?

Recommendation: No recommendation can be made for the use of more than one cycle of HLD for the purpose of reducing microbial contamination.

Rationale: In response to the reported outbreaks of carbapenem-resistant Enterobacterales-associated with endoscopic retrograde cholangiopancreatography procedures between 2013 and 2015, FDA issued recommendations for enhanced processing methods for duodenoscopes to reduce the risk of transmission.[184] Optional supplemental measures after single HLD of the duodenoscopes included double HLD, liquid chemical sterilant processing system, ethylene oxide sterilization, and low-temperature sterilization measures that are legally marketed per FDA. A meta-analysis that included reviewed reports from January 1, 2010 until March 10, 2020 concluded that the contamination rates were dependent on the processing method used.[185] A single HLD resulted in an contamination rate of 16.14% ± 0.019% (95% CI: 12.43%-19.85%). After the use of double HLD or ethylene oxide, the contamination rate decreased to 9.20% ± 0.025% (95% CI: 4.30%-14.10%). However, randomized studies showed comparable contamination rates in the 3 methods (single HLD, double HLD, and HLD/ethylene oxide),[186] and no difference between single HLD and double HLD.[187,188]

34. Instead of HLD, should certain semi-critical devices preferentially be sterilized?

Recommendation:

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 a high risk of transmission of infection to patients.
2. Facilities may choose to evaluate sterilization along with other alternatives to HLD, eg, use of sterile, single use devices (see *36*) or alternative therapeutic or diagnostic modalities as appropriate, while considering infection outcomes, clinical functionality of the devices, feasibility, and patients' access to care.

Rationale: The risk of contamination and pathogen transmission related to specific semi-critical devices, particularly duodenoscopes, is well documented.[146] Alternative strategies to reduce the risk of infection transmission associated with processing of endoscopes (eg, double HLD) generally have not been successful (see *33*).[185–187,189–191] An FDA panel on duodenoscopes in May 2015 discussed the rationale for transitioning from HLD to sterilization for high-risk scopes.[184]

Currently, sterilization processes for endoscopes, which use ethylene oxide gas and hydrogen peroxide gas plasma are legally marketed per FDA; however, they may not be implementable by all facilities or for certain devices. The use of ethylene oxide sterilization on duodenoscopes during infectious outbreaks has been associated with terminating these outbreaks,[192] although ethylene oxide sterilization of clinically used endoscopes has not demonstrated complete microbial eradication.[186] Endoscope contamination with multidrug-resistant organisms has been reported after ethylene oxide sterilization.[192] The length or diameter of lumens and the presence of inorganic salts or organic materials can affect the effectiveness of sterilization with ethylene oxide.[193] Although a sterilizer that uses hydrogen peroxide exists and is legally marketed per FDA, this sterilizer has not been evaluated with clinically used endoscopes.

35. Should facilities choose reusable or sterile, single use duodenoscope components (eg, distal endcaps, elevator mechanisms) and accessories (eg, biopsy port caps, valves, buttons)?

Recommendation:

1. Choose duodenoscope designs that have sterile, single use components and accessories to lower the risk of transmission of infection.
2. Use endoscope components and accessories that are compatible with the endoscope, recommended by the endoscope's MIFU, and are legally marketed per FDA.

Rationale: With data from post-market surveillance studies (also known as 522 studies) revealing challenges in cleaning and disinfection of duodenoscopes, FDA has recommended movement toward device designs that make processing easier and more effective through single use components (eg, distal endcaps, elevator mechanisms) or designs that obviate the need for processing and reuse (eg, single use, flexible endoscopes). As of this publication, several duodenoscopes that facilitate processing with single use components and some duodenoscopes that are fully disposable are legally marketed per FDA.

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Single use components

Single use components lower the risk of HLD failure but do not eliminate the risk of contamination. A randomized clinical trial found reduced contamination in single use elevator cap duodenoscopes following HLD, compared with standard scope designs (3.8% single use versus 11.2% standard) without affecting technical performance and safety of endoscopic retrograde cholangiopancreatography (ERCP).[194]

Single use accessories

Facilities may choose reusable or single use endoscope accessories (eg, biopsy port caps, valves, buttons).[195,196] Some evidence has supported reduced risk of transmission with single use biopsy forceps, compared with reusable biopsy forceps[197] due to challenges in adequate cleaning reusable biopsy forceps.[198] When reusable accessories are used, reprocess them according to MIFU.

In addition to infection prevention considerations, facilities may evaluate how single use products may affect patients' access to care, institutional finances, and the environment. Access to care, financial, and environmental considerations were not included in the scope of this document, and the authors cannot recommend frameworks or models for evaluating them.

36. When available and feasible, should facilities use sterile, single use endoscopes?

Recommendation: 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.

Rationale: The intricate design and configuration of reusable flexible endoscopes or certain components of the endoscope (eg, elevator mechanism) represent significant challenges to effective cleaning and processing. Facilities may not have available resources (eg, physical space, expertise, training, staffing) to support safe processing of reusable endoscopes.

For many procedures that are performed by experienced endoscopists, evidence supports the technical performance of single use duodenoscopes versus reusable duodenoscopes.[199–201] A systematic review of 21 studies of single use flexible ureteroscopes and cystoscopes showed no difference in clinical outcomes.[202]

Investigational devices

37. How should facilities process critical or semi-critical investigational reusable medical devices?

Recommendation:

1. Only use investigational devices following:
   a. Issuance by FDA of an investigational device exemption (IDE) or approval of an investigational new drug (IND) application, *OR*
   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 HLD instructions by both IPC experts and the IRB.
2. When using investigational devices in accordance with the above recommendations, involve IPC in processing protocols developed for investigational reusable medical devices.

Rationale: The FDA and the facility's IRB needs to approve the use of all investigational devices that pose a "significant risk."[92] For devices that are deemed to pose a "non-significant risk" (ie, "a study device does not meet the definition of a significant risk device") the IRB may approve the study without the investigators obtaining an IDE from the FDA. For devices that pose a "non-significant risk," the IRB and IPC should ensure that methods have been established and put in place for processing any investigational reusable medical devices. It should be noted that most healthcare facilities have neither the equipment nor adequately trained HCP to conduct the necessary cleaning and sterilization or HLD validations to be able to establish safe and effective processing.

38. How should 3-dimensional-printed (ie, 3D-printed or additively manufactured) critical or semi-critical reusable medical devices be processed?

Recommendation:

1. Ensure that devices that are 3D-printed are legally marketed per FDA.
2. Follow the validated processing instructions provided in the MIFU.
3. When a 3D-printed device is considered investigational, follow the requirements for investigational devices (see *37*).

Rationale: Devices that are produced using 3D printers may also be referred to as "additively manufactured." These may include a subcategory of devices referred to as "patient-matched devices." Often, these are unique in design. FDA recommends that the manufacturers of 3D-printed devices establish a "design envelope" that effectively brackets the device's design. Once the cleaning and sterilization instructions have been validated on devices that represent the most challenging extremes, these brackets may serve as surrogates, and it can be assumed that these, as well as all intermediate, mid-sized versions of the device, have been adequately evaluated to be legally marketed per FDA.

Experimental, investigational 3D-printed devices that are manufactured onsite should not be used unless they present a "non-significant risk," and the IRB and IPC ensure that methods have been established and put in place for processing these medical devices (see *37*). 3D-printed devices that are manufactured at a healthcare facility are likely to present unique designs for which surrogates are not available as subjects for conducting cleaning and sterilization validations. For example, a study of orthopedic fracture models demonstrated that gas plasma failed to sterilize the inside of a hollow model and steam sterilization deformed the model.[203] Additionally, 3D-printed devices should be manufactured in a manner to ensure that residual manufacturing materials have been reduced to levels that are safe. Most healthcare facilities do not have the equipment and cleaning methods to sufficiently remove manufacturing materials or the adequately trained HCP to conduct cleaning and sterilization or HLD validations.

Tracking reusable medical devices

39. What is the best method for tracking reusable medical devices' preventative and interval maintenance?

Recommendation:

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.
2. Adhere to recordkeeping practices per state and local requirements.

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Rationale: Recordkeeping is needed for both epidemiological tracking and quality control. A tracking system can assist with timely responses to device recalls and monitoring compliance with equipment maintenance requirements.

Handwritten or paper logs can be incomplete, inaccurate, or illegible and are a challenge to use for analytical purposes.[204] Electronic records allow for real-time data extraction and digital queries.[93,205] In addition, newer automated processing models require that HCP enter recordkeeping information before proceeding with the disinfection cycle. Some machines only proceed if parameters are adequate or correct, further reducing the chance of errors.

40. Should a facility replace a reusable medical device (eg, endoscope) with a new device based on time since its initial use, its last maintenance, or the number of uses?

Recommendation:

1. No recommendation can be made for when to replace a device with a new device.
2. Follow the device's MIFU for the service life of the device, including requirements for preventive and interval maintenance.
3. Facilities should not use any devices with known or suspected damage for patient care.

Rationale: Per FDA, MIFUs should include methods for determining the service life of medical devices, such as visual inspections and performance tests. Facilities should adhere to devices' MIFUs for maintenance and testing for their service life.

In reports on outbreaks related to endoscopes, ages of the scopes varied from less than 1 year to 12 years.[169,206–208] Only one study did not find an association between the age of an endoscope and the appearance of damage.[209] Another study found that scopes older than 4 years were more likely to be contaminated, although researchers also found contamination in scopes in use for less than 4 years.[210] Other researchers noted that older scopes were more likely to be contaminated, but the study did not give the ages of the scopes.[77] One study prospectively evaluated new scopes and found damage that required repair within 30 uses,[211] whereas another evaluated scopes at a baseline point in time and found notable damage when they were evaluated 2 months later.[212]

A study that addressed maintenance of scopes found that ureteroscopes that were serviced regularly (every 6 mo) lasted longer (mean of greater than 2 yr) compared with those not routinely serviced (mean of less than 1 yr).[35]

41. Which types of reusable medical devices should facilities routinely track to the patient level?

Recommendation:

1. 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 (eg, duodenoscopes, bronchoscopes).
2. It is at the discretion of the facility to expand tracking beyond the highest risk reusable medical devices.
3. No recommendation can be made for implementing tracking to reduce the risk of transmission or to improve HCP compliance with processing steps, although tracking is often necessary to effectively respond to failures in processing, outbreaks, and product recalls.

Rationale: Although little published evidence exists to support the tracking of reusable medical devices undergoing processing to prevent transmission and infection, the many documented HLD-related outbreaks—in some cases without identification of serious processing errors—suggest that tracking of reusable medical devices is an important step in ensuring that epidemiologic investigations and patient notification are performed rapidly and done efficiently when necessary. Given the practicality of tracking reusable medical devices that undergo HLD, most local and national licensing and accreditation entities consider tracking to be an industry standard-of-care.

Approaches to implementation

42. What visual inspection methods are recommended to ensure debris has been removed?

Recommendation: No standardized and readily implementable methods exist for routine, internal (endoscope channels) visual inspection of reusable medical devices; however:

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 use of lighted magnification to improve the external visualization of reusable medical devices.
2. Send for repair or properly discard any reusable medical devices found to be damaged. Damage can impair function, cleaning, sterilization, and HLD.
3. If a reusable medical device is found to have retained debris, treat it according to the MIFU and reprocess it.
4. If a lumened device is found to have retained debris that cannot be removed:
   a. Do not proceed with reprocessing.
   b. Return the device to the manufacturer for further assessment.
5. When the manufacturer returns the reusable medical device after inspection or repair, follow the MIFU for returning the medical device to service.
6. No recommendation can be made for the use of borescopic examination to assess the integrity of lumened devices before processing.

Rationale: Outbreaks associated with contaminated endoscopes have been linked to identification of luminal damage and retained debris,[213] and identification of debris in processed endoscopes has been significantly correlated with microbiological contamination. Lack of debris has not been similarly correlated with negative microbiologic contamination.[122] Longitudinal analyses have suggested that biofilm accumulates, based on observed increases in staining and debris in endoscopes that were examined over time.[85]

Reusable medical devices requiring sterilization and HLD can be complex in design (eg, crevices, hinges, acute angles, serrated edges, coils, long and narrow lumens). External visual examinations are not adequate to fully identify debris and other damage to reusable medical devices. Visible residue has been reported to be difficult to see after manual cleaning, in part because blood and feces are not easy to distinguish against the dark color of the endoscope. Investigators sampling endoscopes can often detect visible contamination in the effluent or on swabs used during experimental or quality assurance sampling.[196]

Investigators have used lighted, magnifying borescopes and high-resolution video imaging in processed, patient-ready endoscopes to identify retained debris and internal defects, including scratches, non-intact channel lining, discoloration, and damage.

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More than 50% of patient-ready, fully processed endoscopes had scratches, channel shredding, and buckling of lumens. More than a quarter of those sampled also had debris, which were found with enhanced methods such as magnifying borescopes.[122,123,137,214] After manual cleaning and before HLD had been performed, one evaluation observed with a borescope visible irregularities in all clinically used bronchoscopes, including retained fluid, brown, red, or oily residue, scratches, damaged insertion tubes and distal ends, and filamentous debris in channels.[33]

To assess the integrity of reusable medical devices, borescope examination may be a useful method; however, descriptions in the literature are limited, the use of borescopes routinely in clinical practices has not been well-studied, and borescope examinations likely impose substantial costs and training constraints.[33,85,90,123,124,137,212,213] Additionally, there are several unresolved issues with the care and cleaning/disinfection of borescopes that are outside the scope of this guidance. While investigators have used these visualization techniques to perform assessments of cleanliness and microbial contamination for research evaluations or outbreak investigations, the technology is not standardized for routine use. Investigators have proposed scoring systems to better classify the types of damage observed,[123] but these have not been studied or widely adopted. The experience needed to perform these detailed internal visualizations and the lack of a standard lexicon for describing abnormalities and interpreting their relevance are additional barriers to routine implementation.

43. Should HCP participating in sterilization or HLD be educated, trained, and assessed for competency?

Recommendation:

1. Ensure that all HCP are educated, trained, and assessed for competency in sterilization and/or HLD based on their job responsibilities:
   a. Before working independently
   b. When new equipment or when new sterilization or HLD methods are implemented
   c. When processes are changed.
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.
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.

Rationale: The most common cause of processing failures is human error.[104,215] The purpose of training is to educate on how to process devices properly and avoid hazardous exposures and injuries.[216,217] Qualified individuals should train HCP during onboarding and assess their competency.

Initial training is often prolonged and extensive; 31% of facilities surveyed in a study reported that initial training lasted 6 to 12 months.[218] Training should address new items or processes, including the compatibility of supplies and equipment and the processes and procedures validated to achieve the appropriate level of sterilization or disinfection.[219] Facilities may conduct competency assessments to assess skills and to check for training effectiveness. Assessments should be based on objective criteria (eg, steps in the MIFU) and should be able to clearly differentiate HCP who can independently and accurately process reusable medical devices versus those who cannot.[220,221]

Onboarding training is not sufficient alone to ensure ongoing competency. One study found a significant discrepancy between years of experience and technical confidence, versus actual competency of the HCP.[222] As outbreaks of infection continue to occur,[223–225] HCP responsible for processing should receive initial and ongoing competency training.[221] Retraining and refresher sessions on an ongoing basis and when failures are identified[215,226] and assuring compliance with regulatory[227] and accrediting organizations' requirements (eg, The Joint Commission, DNV) serve to reduce processing failures caused by human error.

The optimal frequency of re-training is unclear. It is unknown how long HCP retain initial training, especially with changing equipment and procedures. Two small studies found improved knowledge and practice measures compared with baseline 4 to 7 months after training occurred in 2 of 3 hospitals.[228,229] Studies have shown that re-training is effective when included in response to detected failures and outbreaks.[146,215,226,230]

Insufficient published data exist on how periodic audits affect HCP compliance with processing steps, but infection control rounds and observations by leadership of HCP techniques may reinforce adherence to processes. Auditing tools may also help to verify competency, including in assessing educational needs[231] and in performing self-assessments.[176]

44. What measures reduce the risk of inadequate processing in the implementation of sterilization and HLD?

Recommendation:

1. Review the factors described in the peer-reviewed literature that contribute to common failures in sterilization and HLD. These include the environment where sterilization and HLD activities occur, organizational processes, and individual factors (see *Supplementary Material, Table 7*).
2. Implement effective interventions and best practices to reduce the risk of failure.

Rationale: The literature commonly describes failures in sterilization and HLD that can be categorized into those associated with the environment in which sterilization or HLD take place, the organizational structures in place, and individual HCP factors (see *Supplementary Material, Table 7*).[146,217,232] HCP should be educated in a manner that ensures compliance with the MIFUs of the devices being sterilized or undergoing HLD that focuses on commonly reported errors in processing. Table 7 provides examples of common failures and suggested interventions and best practices to mitigate risk of failure.

45. Should facilities use a centralized or decentralized processing structure?

Recommendation: No recommendation can be made for processing structure; however, facilities should assess the role of centralized or decentralized processing structures in minimizing the risk of processing failures, patient risk, and risk to HCP.

Rationale: The structure of processing may be described as centralized or decentralized. Some facilities employ a hybrid approach, with a portion of processing maintained centrally and a portion decentralized. The organizational structure chosen can impact risk of processing failures and risks to patients and HCP:

1. Centralized processing conducts all processing in one location or utilizes a common oversight structure (eg, shared leadership, competencies) when processing is done in more than one

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location. Centralized processing can assist in standardization, training, and competency assessment, which help to reduce the risk of failures. Centralized processing may support optimization of the physical environment.[233]
2. Decentralized processing does not have a unified organizational structure. Decentralized processing may address challenges related to transport and be perceived as more operationally feasible in ambulatory settings; however, decentralized processing may introduce variability and lack of standardization, which can increase the risk of processing failures.[233]

In reviewing the literature, the authors identified knowledge gaps that, if addressed, could meaningfully impact future approaches to sterilization and HLD. See *Supplementary Material Table 8* for future research considerations.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/ice.2025.41

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