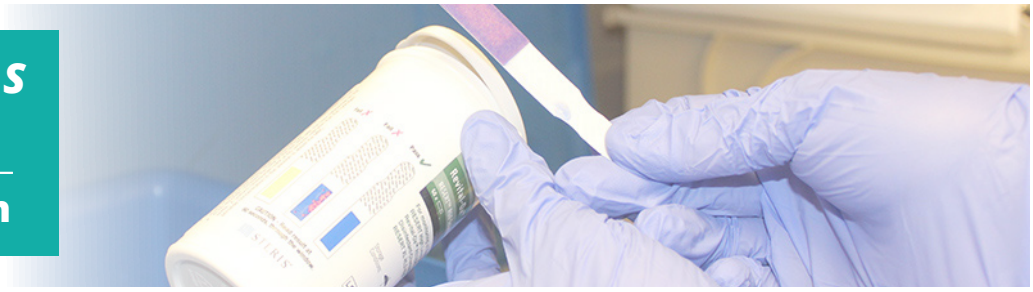
GUIDELINE *ESSENTIALS*
QUICK VIEW

High-Level Disinfection



PRE-PURCHASE EVALUATION

- Evaluate and select US Food and Drug Administration (FDA)-cleared high-level disinfectants before purchase and use.
- Determine if items in the facility that require high-level disinfection (HLD) are compatible with the high-level disinfectant being considered for purchase.
- Perform a health hazard risk assessment of the selected disinfectant.

★ *The health care organization should use a systematic, standardized process when deciding what high-level disinfectants to purchase.*

METHOD AND LOCATION OF PROCESSING

- Whenever possible, sterilize semicritical items.
- Process semicritical items by manual HLD when manual HLD is the only processing method recommended by the manufacturer.
- Process endocavity ultrasound probes by sterilization or by HLD, depending on the planned use of the probe.
- Perform HLD away from patient care areas, including the operating or procedure rooms.
- Perform HLD in an area with limited traffic that is separate from the decontamination area.
- Maintain the processing area's heating, ventilation, and air conditioning system within the system design parameters.

★ *When sterilization is not possible, semicritical items may be processed by HLD by following manufacturer's instructions for use (IFU) in an area intended for processing activities.*

SAFETY

- Wear personal protective equipment (PPE) when handling high-level disinfectants, when performing HLD, or when exposure to potentially infectious material is possible.
- Choose PPE based on the degree of anticipated exposure; PPE may include:
  - a fluid resistant surgical mask
  - a face shield or eye protection
  - a fluid-resistant gown and shoe covers
  - gloves that are made to be used with high-level disinfectants
- Provide safety data sheets (SDS) for each chemical used in the facility and make them readily accessible.

- Develop an emergency spill plan and respiratory protection plan for chemicals listed in the chemical hazard risk assessment.
- Store high-level disinfectants in closed containers and in accordance with:
  - SDS information
  - the manufacturer's IFU
  - federal, state, and local regulations

★ *To maintain the safety of personnel and patients, it is important to follow regulatory guidelines when handling hazardous chemicals such as high-level disinfectants. Eyewash stations should be available in areas where chemicals that are harmful to the eyes are located.*

PREPARATION

- Perform point-of-use treatment immediately after the device is used.
- Transport the contaminated device in a closed and labeled leak-proof, puncture-resistant container, making sure to keep the device moist (eg, with a pretreatment product).
- Perform leak testing for devices that require leak testing in accordance with the device and leak-testing equipment manufacturers' IFU.
- Manually clean the device after leak testing and before performing HLD.
- Rinse and flush the device with utility water in accordance with the manufacturer's IFU.
- Dry the exterior surface with a nonlinting, nonabrasive clean sponge or cloth and purge all channels with pressure-regulated instrument air.
- Use a clean borescope to inspect all channels of the device.
- Prepare high-level disinfectants according to the manufacturer's IFU.
- Use a compatible test strip or other FDA-cleared testing device to determine the concentration of the activated high-level disinfectant.
- Verify that the activated high-level disinfectant is at the temperature recommended by the manufacturer.
- Discard activated high-level disinfectants on or before the reuse-life date.

★ *In preparation for HLD, the high-level disinfectant should be assessed for efficacy, temperature, expiration date, and precipitates or cloudiness.*

MANUAL HLD

- Disassemble and immerse the item in the high-level disinfectant according to the manufacturer's IFU.
- Completely immerse, flush, and fill lumens and ports for the amount of time recommended by the manufacturer.
- Rinse the device with critical or sterile water.
- Use a basin that is large enough to accommodate the volume of rinse water and change the rinse water after each use.

★ *Disassembling the item before HLD, fully immersing and flushing the item in high-level disinfectant, and rinsing the item with critical or sterile water helps ensure the item is disinfected.*

DRYING AND STORAGE

- Dry all external surfaces with a clean or sterile nonlinting cloth and purge all channels with pressure-regulated instrument air or high-efficiency particulate air filtered air.
- Store the device in a way that prevents damage, and use a label that communicates its readiness for use.

- Store devices in a cabinet that is either designed for horizontal storage or of sufficient height, width, and depth to allow the device to hang vertically.
- Wear latex-free gloves when handling or transporting the item that was processed by HLD.

Items that are processed by HLD should be allowed to dry completely to prevent microbial and biofilm formation. If items are stored in a cabinet, the cabinet should be designed for that purpose and located in a clean workroom or in a separate clean area but not in the procedure room.

PROCESSING RECORDS

- Record the following for every device processed by HLD and used in a procedure:
  - Patient identification
  - Procedure date and time
  - Location of use
  - Procedure
  - Proceduralist's name
  - Unique device identifier
- Record the following for each manual HLD process:
  - Name of device and unique device identifier
  - Soaking container identifier
  - Date and time processing was completed
  - Person performing HLD
  - High-level disinfectant solution type, concentration, and expiration date
  - Results of high-level disinfectant testing
  - Temperature and exposure time

Records help to identify trends and compliance. In the event of a processing failure, HLD records also allow for traceability of the item.