Purpose:

High level disinfection of Cystoscopes is essential for ensuring Cystoscopy instruments do not transmit infectious pathogens to patients. Cystoscopy is one of the most commonly performed procedures in the urology office setting, and is an invaluable tool in identifying lower urinary tract pathology. Cystoscopy procedures can be performed using the rigid cystoscope or the flexible cystoscope, depending upon need and preference of practicing physician. Both the rigid cystoscope and the flexible cystoscope require a specific cleaning process in order to reduce the microbial count and ensure that High Level Disinfection (HDL) is completed appropriately. Disinfection may be high level, intermediate level or low level. The level of disinfection required is governed by the intended use of the item, namely in a ‘non-critical’, ‘semi-critical’ or ‘critical’ site (refer to ‘Spaulding’s classification’). Under the Spaulding classification system, cystoscopes are considered semi-critical devices. High level disinfection of previously cleaned instruments and equipment will produce items with very low likelihood of any pathogenic microorganisms remaining.

Policy:

1. At Premier Medical Group, urology healthcare employees are responsible for cleaning, reprocessing and preparing cystoscopes for patient use. The process will be consistent from office to office. This includes standardized reprocessing steps for cleaning, high-level disinfection and/or sterilization. Written policy and procedure is established and reviewed regularly. This document is readily available in the practice area. Pertinent Healthcare employees will be trained in these practices during orientation. Ongoing educational programs and annual review for these pertinent healthcare employees will be implemented to foster a safe atmosphere for patients and healthcare employees.

2. It is important that only healthcare employees trained in instrument handling and processing should be tasked with reprocessing cystoscopic equipment. Initial and ongoing training should be documented, as damage to a cystoscope may result in loss of the instrument’s integrity with subsequent contamination. Healthcare Employees should follow manufacturer-supplied written instructions on handling, cleaning and reprocessing. The reprocessing procedures should be appropriate to the practice setting and based on availability, product compatibility, cost, healthcare worker safety and turnaround time.
Procedure:
Under the Spaulding classification system, cystoscopes are considered semi-critical devices.

Semi-Critical Devices:
- Contact intact mucous membranes, do not penetrate body surfaces
- Require high-level disinfection or sterilization
- Rationale - Intact mucous membranes resist common bacterial spores but are susceptible to other organisms

Sterilization:
Sterilization involves the complete destruction of all microbial life, including bacterial spores. There are several types of sterilization processes available, including steam under pressure, ozone, ethylene oxide gas, hydrogen peroxide gas plasma (e.g., Sterrad, V-Pro), and liquid chemicals (e.g., Steris System 1). Some methods of sterilization may not be compatible with flexible endoscopes.

Disinfection:
- Disinfection is defined as thermal or chemical destruction of pathogenic and other types of microorganisms.
- Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g. bacterial spores). High-level disinfection (HLD) has the ability to kill all micro-organisms, except large numbers of bacterial spores.
- Spores are a defense mechanism of some bacteria and are resistant to high-level disinfectants unless they are exposed for an extended period. However, most high-level disinfectants have the ability to sterilize given sufficient exposure time.

High level disinfection or sterilization:

*High-level disinfection is the minimum level of disinfection recommended for cystoscopes:*
The decision to either high-level disinfect or sterilize a cystoscope and accessories is dependent on material compatibility, the standard of practice, the availability of the sterilizer and the time constraints needed to reprocess the devices. Each office of Premier Medical Group should establish a “standard of practice” that they can achieve consistently to deliver the same level of care to all patients.

Reprocessing of flexible cystoscopies- Steps:

Step 1: Pre-cleaning
A. Pre-cleaning should be done to remove and loosen debris before manual cleaning is performed. To prevent drying of secretions and make the contaminated cystoscope safe to handle, this pre-cleaning should begin promptly after the cystoscope is removed from the patient. Standard universal precautions should be followed and personal protective equipment (for example, gloves and eyewear) should be worn. Gross debris should be wiped off the outside surface using a soft, disposable cloth or sponge, and water or enzymatic detergent should be flushed through the channels.
Step 2: Leak testing for flexible cystoscopes:

B. After the initial pre-cleaning, a leak test should be performed to ensure that the flexible covering and the internal channels are intact. A special device designed for leak testing should be attached to the scope and pressurized, and the scope should be submerged to test for leaks. Even a tiny hole can be a potential contamination source by allowing fluid entry that will accumulate during repeated use and processing. Leak testing and inspection are the only ways for early detection of fluid invasion. If a leak is detected, contact the cystoscope manufacturer for specific instructions about decontaminating and returning the device for repair. Certain flexible cystoscopes may have a proprietary seal that precludes leak testing. In such instances, users should follow the manufacturer’s instructions to assess for instrument damage.

Step 3: Cleaning

C. Cleaning removes all visible soil and significantly reduces the bio burden in order to facilitate the biocidal process. The interior and exterior of the cystoscope must be meticulously cleaned. This is vital to the effectiveness of subsequent microbiocidal processes used for disinfection or sterilization. The cystoscope should be disassembled so that cleaning and removal of all protein material can be accomplished. All detachable parts of the cystoscope such as valves, adapters and caps should be removed according to the manufacturer’s instructions for use.

D. Users should check the instructions for use or operator’s manual for the cystoscope for specific instructions on cleaning, disinfection and/or sterilization. Devices must be disassembled properly to ensure adequate reprocessing. The cleaning process involves the entire instrument. Channels, or lumens, should be flushed and/or brushed to remove all debris. Devices should be cleaned promptly following the procedure to prevent bio burden from drying, which makes it more difficult to remove.

E. Cleaning should be done by using a recommended enzymatic detergent, which assists the cleaning process by breaking down the bio burden. Since cystoscopes and accessories are exposed to blood (protein) and irrigation solutions, the enzymatic cleaner should be able to digest proteins and sugars. Enzymatic detergents are chemicals that must be used according to label instructions in order to maintain their potency. They can be rendered ineffective by temperatures that are too high or too low, or if the concentration is incorrect. Additional products should not be mixed with enzymatic solutions; this may cause a chemical reaction that could damage the devices or render the solution ineffective. The used enzymatic detergent should be discarded after each use.

F. The cleaning solution should contact all external and internal surfaces of the device being cleaned. It is important to follow the contact time, temperature and concentration recommended by the manufacturer of the cleaning solution to ensure effective cleaning. The lumens should be flushed and brushed to remove organic material (blood, tissue, etc.). Auxiliary channels should be cleaned, even if they have not been used in the examination. The brush should be appropriate to the diameter of the lumen and should be passed through the lumen under water (to minimize aerosolization). The bristles should be cleaned before retracting the brush back through the lumen. Reusable brushes should undergo HLD after each use. A soft cloth or brush should be used to clean the external surface. Abrasive cleaners should never be used, as abrasions and dents can create a location for micro-organisms to collect and multiply.

G. Following the cleaning process, all parts of the cystoscope should be thoroughly rinsed to remove any residues that may interfere with the efficacy of the HLD or sterilization process. Water (distilled, deionized or tap water) may be used for rinsing. The rinsing solution should not be reused.
Step 4: Disinfection

H. As noted above, the minimum recommended practice for flexible and rigid cystoscopies, and their accessories is HLD with a liquid sterilant/disinfectant approved by the U.S. Food and Drug Administration (FDA). Alternatively, PMG may choose to sterilize the scopes when the necessary materials are available. Multiple high-level disinfectants exist, and the required exposure times and temperatures vary according to the agent that is used.

a) All products should be used according to the directions on the label regarding concentration, rinsing and re-use. Always confirm that the device is compatible (will not be damaged by the chemical) prior to use. If the endoscope manufacturer warns against using a specific agent because it may cause functional damage, then that chemical agent should be avoided.

b) A current list of disinfectants/ sterilants that are approved for use with flexible cysto/endoscopes is available on the FDA Web site (http://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofsinglerecycledevices/ucm133514.htm).

The efficacy of disinfectants depends on the following factors:

1) Number /type of microbes present
2) Effectiveness of pre-cleaning before disinfection
3) Active ingredients of the chemical agent
4) Concentration level of the disinfection solution
5) Temperature and pH of the chemical agent
6) Contact time with the chemical agent
7) Water hardness
8) Inorganic matter present

- To ensure adequate disinfection, it is important that the manufacturer’s recommendations regarding these factors be followed. Importantly, devices that are decontaminated by a high-level disinfectant should be used immediately following the process because a safe disinfection level cannot be guaranteed if the device is stored. Therefore, a cystoscope that undergoes HLD and is then stored overnight should undergo repeat HLD prior to reuse.

Manual vs. Automated Disinfection:

- In manual disinfection, the cystoscope is manually immersed in a covered basin containing a chemical disinfectant. (Currently we use Metricide 28) The entire scope, including the head, should be immersed completely and all channels should be filled with disinfectant. This can be accomplished by suctioning the solution through each channel with a syringe. It is important that manufacturer’s recommendations regarding correct concentration, temperature, and contact time are followed to ensure adequate disinfection. The disinfectant/ sterilant should be tested to verify minimal effective concentration (MEC) of the active ingredient. The manufacturer instructions direct that this testing be performed prior to each use. If the testing indicates that the concentration is less than the MEC, the solution should be discarded. The solution should also be discarded at the end of its reuse life, regardless of the MEC. Adding new liquid sterilant/disinfectant solution to keep the basin filled (“topping off”) does not extend the reuse life of the agent.
STEP 5: Rinsing
A. After manual disinfection has been performed, cystoscopes will be thoroughly rinsed and channels flushed to ensure that all traces of the disinfectant solution are adequately removed. Rinsing may be done with sterile water for at least one and a half minutes and channels flushed with a minimum of 100cc’s of water.

STEP 6: Drying
B. Drying the cystoscope after each reprocessing cycle, both between patient procedures and before storage, is a requisite practice that is crucial to the prevention of bacterial transmission. The exterior surfaces should be dried with a soft, lint-free towel, while the channels should be purged with air until dry. After drying, rigid cystoscope lenses should be polished using a circular pattern with 70% alcohol, and a cotton tipped applicator.

STEP 7: Storage
C. Flexible cystoscopes should be stored in a manner that will protect them from damage and contamination. Removable parts (valves, stopcocks, etc.) should not be attached to the cystoscope during storage. They should be stored in a protected, well-ventilated area. The cystoscopes shipping container should not be used for storage, as bacteria can proliferate in its dark, moist environment. Protocols should be developed to ensure that users can readily identify a cystoscope that has been properly processed and is ready for patient use.

5. Reprocessing of Rigid Cystoscopes
• The reprocessing steps for rigid cystoscopes are similar to those involved for flexible instruments, but no leak testing is required. In the outpatient environment the rigid instruments are processed via HLD using the same Metricide 28 that is used for flexible cystoscopes.

Safety considerations/Employee safety
• Only individuals trained in decontamination and disinfection of semi-critical medical devices and handling of liquid chemical germicides should process instruments. Exposure to glutaraldehyde and ortho-phthalaldehyde is harmful if swallowed, inhaled or absorbed by the skin. Skin soreness, itching, rashes, blistering, irritation to the eyes, or difficulty breathing should be reported to a supervisor. Users should refer to the Safety Data Sheet (SDS) for first aid measures.

Monitoring Germicide:
• Appropriate test strips are utilized to ensure that the germicide is above its MEC. Results should be recorded in the log book that can be consulted for auditing purposes. The expiration date for the germicide and test strips should be checked regularly, and these products are not to be used beyond the expiration date. Use of a thermometer and timer can ensure that optimum reprocessing conditions are met.

Log book
• The log book is a useful tool to document reprocessing procedures and to demonstrate compliance with regulatory requirements. The log book should include date, time, identification of items to be soaked, time the cystoscope was placed in the solution and the name of person performing the cleaning and dilution testing results.
Environment:
- The following items should be available: enzymatic cleaner, soft-bristle brushes, syringes, cleaning cloths and alcohol. A sink is required to manually clean cystoscope prior to disinfection. The germicide solution container should be of sufficient size to totally immerse the scope and be tightly covered and labeled with the name of the solution and the expiration date. Eating, drinking and smoking are prohibited in any area where germicide is handled.

Personal Protective Equipment:
- When working with germicide, the following personal protective equipment is recommended:
  - Eyes: Splash goggles/face shield
  - Skin: Protective gloves (nitrite or butyl rubber for glutaraldehyde solutions)
  - Clothing: Protective gown with long sleeves or chemical protective apron
- In addition, hands should always be washed after handling germicide and when removing personal protective equipment

Disposal:
- Spills should be cleaned up immediately per manufacturer recommendations.

Specific Patient Safety Concerns:
Patients with Drug Resistant Infections
In patients known to be infected or colonized with multi-drug resistant organisms (such as methicillin-resistant Staphylococcus aureus [MRSA]) or with documented human immunodeficiency virus (HIV) infection, the standard reprocessing procedures described above are sufficient to completely eradicate these organisms, and no additional reprocessing steps are necessary.

Date Policy to be reviewed: 12/15