

Joint AUA/SUNA White Paper on the REPROCESSING OF FLEXIBLE CYSTOSCOPES

ALERT

(2/8/14): The STERIS System 1E (SS1E) liquid chemical sterilant processing system has become available for reusable processing heat-sensitive devices and their accessories that cannot be processed using thermal methods (Page 8).

Additionally, new evidence indicates properly processed cystoscopes can now be stored 7-10 days before reprocessing is necessary (Page 9).

New References:

Rutala WA and Weber DJ. New developments in reprocessing semicritical items. *Am J Infec Control* 2013;41:S60-S66.

Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 20911. *Gastrointestinal Endoscopy* 2011;73(6): 1075-84.

Edits made to the original white paper in 2014 are noted in italics.



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INTRODUCTION

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. The development of flexible endoscopic technology has allowed the procedure to be performed using flexible instrumentation, which reduces patient discomfort and allows the procedure to be performed in the supine position. While office flexible cystoscopy has become a standard urology procedure, it is important to acknowledge that the flexible cystoscope is a complex instrument that requires reprocessing between patients. Numerous federal bodies and professional societies have produced guidelines and standards for the reprocessing of endoscopes, but few specifically address the reprocessing of cystoscopes. This joint AUA-SUNA white paper presents a brief overview of the current guidelines for reprocessing of flexible cystoscopes, and highlights particular aspects of instrument reprocessing that are unique to cystoscopy.

2. PERSONNEL/ TRAINING

In many clinical settings, urology office staff are responsible for cleaning, reprocessing and preparing cystoscopes for patient use. The process should be consistent from office to office. This includes standardized reprocessing steps for cleaning, high-level disinfection and/or sterilization. Written policies and procedures should be established in all healthcare settings and should be reviewed regularly. These documents should be readily available in the practice area. Employees should be trained in these practices during orientation. Ongoing educational programs for personnel should be developed to foster a safe and positive atmosphere for patients and staff.

It is important that only personnel 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. Records should be maintained of daily compliance. Staff 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.

3. BACKGROUND

Earle Spaulding developed a classification system looking at how devices were used and what impact they had on transmitting infection. Although his system was defined in 1968, it is still used today with some minor modifications. Under the Spaulding classification system, cystoscopes are considered semi-critical devices.

Noncritical devices:

Contact intact skin only

May be cleaned with low-level disinfection

Examples: Blood pressure cuffs, tables

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

Examples: cystoscopes, respiratory therapy equipment, anesthesia equipment, bronchoscopes, GI endoscopes

Critical devices:

Introduced into bloodstream or other normally sterile areas

Risk of infection is high

Sterilization is required

Examples: surgical instruments, biopsy forceps, laparoscopes, cardiac and urinary catheters

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.

Intermediate-level disinfection inactivates *M. tuberculosis*, vegetative bacteria, most viruses, and most fungi but it does not necessarily kill bacterial spores.

Low-level disinfection can kill most bacteria, some viruses, and some fungi, but it cannot be relied upon to kill resistant microorganisms such as tubercle bacilli or bacterial spores.

High-level disinfection is the minimum level of disinfection recommended for cystoscopes.

HIGH LEVEL DISINFECTION OR STERILIZATION?

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 facility should establish a “standard of practice” that they can achieve consistently to deliver the same level of care to all patients.

4. REPROCESSING OF FLEXIBLE CYSTOSCOPES – STEPS

STEP 1: PRECLEANING

Precleaning 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 precleaning 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

After the initial precleaning, 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

Cleaning removes all visible soil and significantly reduces the bioburden 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 microbicidal 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.

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 bioburden from drying, which makes it more difficult to remove.

Cleaning should be done by using a recommended enzymatic detergent, which assists the cleaning process by breaking down the bioburden. 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.

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. Reuseable 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.

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

As noted above, the minimum recommended practice for cystoscopes is HLD with a liquid sterilant/disinfectant approved by the U.S. Food and Drug Administration (FDA). Alternatively, users 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. 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. Details for commonly used disinfectants/sterilants are provided below. Products may become available that were not in existence when this document was written. A current list of disinfectants/sterilants that are approved for use with flexible endoscopes is available on the FDA Web site (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofsingle-usedevices/ucm133514.htm>).

The efficacy of disinfectants depends on the following factors:

- Number /type of microbes present
- Effectiveness of precleaning before disinfection
- Active ingredients of the chemical agent
- Concentration level of the disinfection solution
- Temperature and pH of the chemical agent
- Contact time with the chemical agent
- Water hardness
- 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. 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.

An automated endoscope reprocessor (AER) may be used as a substitute for manual cleaning in some circumstances. AER's are closed systems that store the chemical disinfectant in an enclosed internal reservoir and automatically transfer it to an enclosed reprocessing chamber during chemical immersion of the endoscope. AERs automate and standardize several important reprocessing steps, and reduce exposure of personnel to the chemical disinfectants. Note that if cycles/phases are interrupted, HLD cannot be ensured and the full cycle must be repeated. Certain AERs are only compatible with specific chemical disinfectants. Most AERs on the market were developed for use with gastrointestinal endoscopes. Therefore, users who are considering the use of an AER for reprocessing cystoscopes should check with the AER manufacturer as well as the cystoscope manufacturer to ensure compatibility.

Commonly Used Chemical Disinfectants

Always check with the endoscope manufacturer before using any chemical disinfectant to ensure material compatibility.

1. Glutaraldehyde

Glutaraldehyde has been used for more than 30 years in many healthcare settings for HLD and sterilization, and is the most widely used chemical for HLD of flexible cystoscopes. It is an irritant and some individuals develop acute sensitivities (skin irritation, irritation to eyes, asthma-like symptoms) during use. Glutaraldehyde may be used in manual or automated reprocessing protocols. Glutaraldehyde products are marketed under a variety of names and are available in a variety of concentrations (2.4-3.4 percent). Glutaraldehyde is also included in some disinfectant solutions that contain multiple active ingredients.

The required soak time and temperature for attaining HLD vary from agent to agent, and the FDA-cleared manufacturer's recommendations should be followed. The recommended soak time for HLD with 2.4 percent glutaraldehyde at room temperature is 45 minutes. However, multiple scientific studies and professional organizations support the efficacy of >2 percent glutaraldehyde for 20 minutes at room temperature. This recommendation differs from the label claim because the federal labeling regulation assumes no cleaning of the medical device prior to chemical exposure. In contrast, the studies that support a 20-minute soak time assume adequate cleaning prior to disinfection. In 2008, the Centers for Disease Control (CDC) released its "*Guideline for Disinfection & Sterilization in Healthcare Facilities.*" This document supports the stance that a 20-minute exposure in a high-level disinfectant is sufficient to achieve the appropriate level of microbiocidal activity, if the device is appropriately precleaned.

Glutaraldehyde Solutions and Surfactants

Glutaraldehyde solutions are available with or without surfactants. Surfactants are soaps that break down the surface tension and allow the solution to penetrate small areas. The presence of surfactants has no clear effect on the efficacy of the disinfection process, but they may prolong the use-life of a high-level disinfectant. Most glutaraldehyde solutions with use-lives longer than 14 days contain surfactants. Unfortunately, surfactants are more difficult to rinse away, and therefore they may leave a residue on the device, which could cause irritation to patients or staff. Residual surfactants can also be conductive to electrical currents, may prohibit small endoscope joints from moving freely and may potentially cause damage to endoscopes. Prior to using glutaraldehyde solutions with surfactants, users should confirm compatibility with the specific cystoscope that is used.

2. Ortho-phthalaldehyde

Ortho-phthalaldehyde 0.55 percent (OPA) was introduced to the market in 1999. Like glutaraldehyde, it is a potential irritant of eyes, skin, nose and other tissues. OPA is cleared by the FDA as a high-level disinfectant at an immersion time of 12 minutes at 20°C and 5 minutes at 25°C. Multiple studies have documented excellent microbiocidal activity. However, anaphylactic reactions have been reported in patients with bladder cancer who underwent repeated cystoscopy using scopes that were sterilized with this agent (see Patient Safety section), and consequently, OPA is contraindicated in patients with a history of bladder cancer. OPA may be used in manual or automated reprocessing protocols.

3. Peracetic acid

*The STERIS System 1E (SS1E) liquid chemical sterilant processing system can be used to process reusable **heat-sensitive devices** such as endoscopes and their accessories that cannot be processed using thermal methods. SS1E uses the S40 chemical sterilant, a peracetic acid germicide along with tap water that has been filtered and exposed to ultraviolet rays to minimize bioburden. A device processed using SS1E is considered to be liquid chemically sterilized. The processed devices should be used immediately or stored in a manner similar to that of high level disinfected endoscopes.*

4. Hydrogen peroxide

A premixed, ready-to-use chemical that contains 7.5 percent hydrogen peroxide (Sporox™ and EndoSpor) is FDA-approved for HLD (30 minute soak at room temperature). This solution may be used in manual or automated reprocessing protocols. The solution is highly acidic, and most flexible cystoscope manufacturers recommend against using acidic products due to potential damage to the instrument. Users should check with their cystoscope manufacturer for specific recommendations.

5. Other agents

Steam sterilization utilizes high temperatures, commonly about 270-275° F, under a vacuum to destroy organisms. Currently there are no flexible cystoscopes that can be sterilized in a steam sterilizer, but rigid cystoscopes and many accessories are compatible with steam. Devices exposed to steam must be heat- and moisture- stable. If these items are packaged appropriately, the items can be stored sterile for use at a later date. Other methods for sterilization include ethylene oxide gas and hydrogen peroxide plasma vapor (Sterrad®), although they are not commonly found in an office environment due to cost and regulatory issues.

STEP 5: RINSING

After manual or automated disinfection has been performed, cystoscopes should 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, filtered water, or tap water. If tap water is used for rinsing, then the instrument should also be rinsed with ethyl or isopropyl alcohol after the tap water rinse. Rinse water should be discarded after each use.

STEP 6: DRYING

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.

STEP 7: STORAGE

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. Scopes should be hung in a protected area that will facilitate thorough drying. If it is not possible to hang the scopes, they should be stored in a well-ventilated area. The cystoscope's 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. *The maximum acceptable storage interval before reprocessing becomes necessary has not been well defined, but 7-10 days appears safe.*^{9,10}

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 hospital setting, steam sterilization is often employed, but in the outpatient environment it is common for rigid instruments to be processed via HLD using the same chemicals (glutaraldehyde, OPA, etc.) that are used for flexible cystoscopes.

6. 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 Materials Safety Data Sheet (MSDS) for first aid measures.

MONITORING GERMICIDE

Appropriate test strips should be utilized to ensure that the germicide is above its MEC. Results should be recorded in a 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 should not be used beyond the expiration date. Use of a thermometer and timer can ensure that optimum reprocessing conditions are met.

LOG BOOK

A log book is useful to document reprocessing procedures and to demonstrate compliance with regulatory requirements. A separate log for each disinfectant basin is recommended. The log book should include date, time, cystoscope identification, method of cleaning, time the cystoscope was placed in the solution and time that it was removed, serial/identification number of automatic endoscope reprocessor (if used), name of person performing the cleaning, dilution testing results, routine and unscheduled maintenance or repairs and disposition of defective equipment.

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 should be used in a well-ventilated environment or in an exhaust hood or ductless fume hood with appropriate filter. 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 should be prohibited in any area where germicide is handled. Ideally, cleaning and reprocessing should be conducted after the patient has exited the procedure room.

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

Respirators: Follow OSHA Respiratory Protection Standard (1910.134)

In addition, hands should always be washed after handling germicide and when removing personal protective equipment

Disposal

Spills should be cleaned up immediately. The use of a pre-configured “Spill Kit” helps to facilitate quick cleaning. Germicides should be disposed of according to state and local disposal regulations. Empty containers should not be reused.

Specific Patient Safety Concerns

Bladder Cancer Patients

In April 2004, the manufacturer of Cidex OPA disseminated information to users about anaphylaxis-like reactions experienced by patients with bladder cancer undergoing repeated cystoscopy. According to the CDC, of approximately 1 million urologic procedures performed using instruments reprocessed using Cidex OPA, 24 cases of anaphylaxis-like reactions have been reported after repeated cystoscopy (typically after four to nine treatments) in patients with a history of bladder cancer. As a result, the manufacturer’s label was changed to include a contraindication that OPA is not to be used to process any urological instrumentation used to treat patients with a history of bladder cancer.

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.

7. DISPOSABLE ENDOSCOPE SHEATHS

Video cystoscopes with sterile, single-use, disposable endoscope sheaths are currently available. These sheaths may limit the need for HLD between procedures and thereby reduce reprocessing time and potentially prolong the cystoscope lifespan. Following each procedure, the sheath should be inspected to confirm its integrity, and then it must be carefully removed and discarded. Leak testing of the cystoscope should be performed after each use. Intermediate-level disinfection is considered adequate if the sheath has remained intact; this consists of washing the external surfaces with a detergent, rinsing with water, wiping the external surfaces with 70 percent alcohol, and drying the instrument. It is important to note that if the disposable sheath is torn or the cystoscope is grossly contaminated, it should be high-level disinfected or sterilized.

8. REUSE OF SINGLE-USE ITEMS

For cystoscopy and other medical procedures, the reuse of single-use or ‘disposable’ items (e.g. tubing, irrigation solution, biopsy forceps) may be considered as a cost-savings measure, but this practice is controversial. Some investigators have demonstrated that it is safe to reuse disposable medical devices such as cardiac catheters, but more studies are needed in order to better define the risks and benefits across a variety of products. Given the controversial nature of this practice, the FDA has issued guidelines stating that hospitals or other entities who intend to reuse items that are approved for single-use only will be considered to be device “manufacturers” and will be regulated in the same manner. A reused product will have to comply with the same regulatory requirements of the product when it was originally manufactured, and third-party reprocessors must demonstrate that the safety, efficacy, and integrity of the product have not been compromised by the reprocessing procedure. Since this practice has been most widespread in acute-care hospitals, the guidelines were written to apply only to acute-care hospitals. However, the FDA has stated their intentions of extending the guidelines to other healthcare settings in the future.

Urology practices considering the reuse of single-use or disposable items during cystoscopy should seek specific policies and regulations from their state Department of Health, Board of Medical Examiners and Board of Nursing.

REFERENCES

1. Bowles S, Foley F, Page M, and Seidel S. Cystoscopy: Disinfection/sterilization-clinical practice guideline. In: Cysto room survival manual: guidelines for urologic endoscopy. Edited by M Page. Pitman, NJ: Society of Urologic Nurses and Associates, Inc. 2007; pp. 5-9.
2. Rutala WA, Weber DJ, and the Healthcare Infection Control Practices Advisory Committee. CDC guideline for disinfection and sterilization in healthcare facilities, 2008. Available at: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed October 14, 2009.
3. FDA Food and Drug Administration. FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices - March 2009. Available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM133514>. Accessed October 14, 2009.
4. OSHA Occupational Safety and Health Administration. Best practices for the use of glutaraldehyde in health care 2006. Available at: <http://www.osha.gov/Publications/glutaraldehyde.pdf>. Accessed October 14, 2009.
5. OSHA Occupational Safety and Health Administration. Glutaraldehyde hospital e-tool – healthcare wide hazards module. Available at: <http://www.osha.gov/SLTC/etools/hospital/hazards/glutaraldehyde/glut.html>. Accessed October 14, 2009.
6. OSHA Occupational Safety and Health Administration. Process Safety Management of Highly Hazardous Chemicals -- Compliance Guidelines and Enforcement Procedures." Available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=1559. Accessed November 3, 2009.
7. NIOSH National Institute for Occupational Safety and Health. Glutaraldehyde- occupational hazards in hospitals, NIOSH Publication No. 2001-115. Available at: <http://www.cdc.gov/niosh/docs/2001-115/>. Accessed October 14, 2009.
8. FDA Notice: Concerns About the Steris System 1 Processor, Components, and Accessories, and FDA Recommendations. Available at: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191585.htm>. Accessed December 8, 2009.
9. Rutala WA and Weber DJ. New developments in reprocessing semicritical items. Am J Infec Control 2013;41:S60-S66.
10. Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 20911. Gastrointestinal Endoscopy 2011;73(6): 1075-84.

In-Office Disinfection of Flexible Cystoscopes
Quick Reference Tool

GATHER		
MATERIALS		
<input type="checkbox"/> Soft cloth or disposable sponge	<input type="checkbox"/> Face shield or goggles	<input type="checkbox"/> Timer
<input type="checkbox"/> Large container with enzymatic detergent solution	<input type="checkbox"/> Protective gown or apron	<input type="checkbox"/> Lint-free cloth
<input type="checkbox"/> Gloves (Butyl, Nitrile for glutaraldehyde)	<input type="checkbox"/> Soaking cap (if applicable)	<input type="checkbox"/> 70% Alcohol (Isopropyl or Ethyl)
	<input type="checkbox"/> Leakage tester	<input type="checkbox"/> Syringes for suctioning and drying
	<input type="checkbox"/> Activated high-level disinfectant/sterilant in covered soaking tray with adequate volume to fully immerse scopes	

1. Preclean – After use, promptly wipe entire housing and shaft with moistened sponge and flush water through channel.
2. Leak Test – Follow manufacturer’s instructions to confirm integrity of scope.
3. Manual cleaning
 - Remove any seals or stopcocks and attach any cleaning adapters if required.
 - Totally immerse the flexible cystoscope, including the head, in an enzymatic detergent that is mixed according to the label directions.
 - Clean all exterior surfaces with a soft cloth.
 - Flush and brush all channels.
 - Thoroughly rinse with clean water.
4. High-level disinfection
 - Test solution for Minimum Effective Concentration and document.
 - Totally immerse cystoscope, including the head, in high-level disinfectant (HLD) prepared according to manufacturer’s instructions.
 - Fill all channels with disinfectant by suctioning solution through channel with a syringe.
 - Set timer for specified immersion time.
 - Document immersion time.
5. Rinsing
 - Remove cystoscope from HLD and drain excess solution.
 - Thoroughly rinse exterior and channels with water.
 - Note: if tap water is used, flush channels with alcohol to aid in drying and inhibit bacterial growth from tap water.
6. Drying
 - Dry exterior surfaces with a soft, lint-free towel.
 - Purge channels with air until dry.
7. Storage
 - Hang scopes to thoroughly dry whenever possible.*

**Scopes cleaned with HLD and stored overnight should be re-cleaned prior to reuse*