



Disinfection of Flexible Endoscopes in Automatic Reprocessors Using a Single-Use Disinfectant

OPA Concentrate

Effective infection prevention is not only an axiom of patient safety, but also an economic necessity for hospitals, outpatient surgery centers, and other medical facilities. Congress recently passed legislation requiring the Centers for Medicare & Medicaid Services (CMS) to identify serious, preventable hospital-acquired conditions for which Medicare would no longer reimburse after October 1, 2008.¹ Several hospital-acquired infections occupy a premier place on the resulting list.

Although many hospital-acquired infections are related to urinary and vascular catheters, infection prevention professionals also have long focused on the risks of infection associated with endoscopic procedures. More than 10 million gastrointestinal endoscopic and 500,000 flexible bronchoscopic procedures are performed in the United States every year.^{2,3} The instruments used for these procedures contact mucous membranes in areas of the body that are not normally sterile and, therefore, must undergo thorough cleaning and high-level disinfection between uses.³

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Accordingly, rigorous infection prevention protocols for hospitals, endoscopy suites and centers are key. The materials and procedures by which endoscopes are rendered pathogen-free become highly relevant to the infection control profile of the entire hospital. Thus, not only is effective

high-level disinfection of these devices essential to quality patient care but also to risk management and finance areas as well. As a result, it is imperative that only the most thoroughly studied, evidence-based materials and methods are used.

Effective Endoscope Reprocessing

To date, all published episodes of pathogen transmission related to GI endoscopy can be traced to either a failure to follow established cleaning and disinfection/sterilization guidelines or the use of defective equipment.³ Consequently, special attention is now directed toward maintaining good general infection prevention practices through strict adherence to endoscope reprocessing guidelines, such as those created by the American Society for Gastrointestinal Endoscopy, the Society of Gastroenterology Nurses and Associates, and other organizations.³

Because a single flexible endoscope might be used 300–1,200 times a year, many busy endoscopy centers and gastroenterology departments have adopted automatic endoscope reprocessors (AERs), not only to reduce staff time and workload spent on this task but

also to ensure consistent, effective results. Automatic endoscope reprocessors expose flexible endoscopes to a chemical disinfectant at a specified temperature for a specified duration in order to achieve high-level disinfection for every instrument, every time. Some new AERs also automate cleaning of instruments prior to the disinfection process. Using an enzymatic detergent, these new AERs decrease the bioburden and organic soil that can interfere with high-level disinfection and eliminate the human variability associated with manual cleaning of endoscopes.

For delicate and costly flexible endoscopes, high-level disinfectants must be effective and also provide a high level of materials compatibility. CIDEX® OPA Concentrate Solution (Advanced Sterilization Products [ASP], Division of Ethicon, Inc.) combines the efficacy and materials compatibility previously demonstrated in validation tests of CIDEX® OPA Solution with a unique single-use formulation designed for ASP's automatic endoscope reprocessors, ensuring that each endoscope receives fresh disinfectant every time.

CIDEX® OPA Concentrate Solution

CIDEX® OPA Concentrate Solution provides fast, safe, and effective high-level disinfection of flexible endoscopes in ASP's automatic endoscope reprocessor systems, including the EVOTECH™ Endoscope Cleaner and Reprocessor and the AdaptaScope™ System. These reprocessors automatically inject CIDEX OPA Concentrate Solution for dilution to the appropriate concentration to achieve high-level disinfection with a 5-minute exposure at a minimum of 50° C (the non-concentrate CIDEX® OPA Solution achieves high-level disinfection in 5 minutes at 25° C in an automatic endoscope reprocessor). This rapid disinfection contributes to a fast, automated processing time of 33 minutes or less, depending on the system and cycle used.

CIDEX OPA Concentrate is based on the well-studied CIDEX OPA Solution, which has been shown over nearly 10 years of clinical use and testing to be effective against a variety of microorganisms and compatible with a broad range of materials. CIDEX OPA Concentrate Solution is cleared for marketing in the United States and also has been on the international market since 2003. Minimum effective concentration (MEC) of the solution is automatically monitored in the AER systems, obviating the need for manual testing, and the automated, single-use formulation minimizes contact between personnel and disinfectant.

Single-Use Formulation

CIDEX® OPA Concentrate Solution is ready to use, requiring no activation. A predetermined amount of the solution is automatically injected into the processor

basin and diluted to a predetermined in-use concentration (minimum 0.055% *ortho*-phthalaldehyde) in the basin. It then circulates at 50° C for 5 minutes through every channel of the endoscope and over all exterior surfaces. Using a single-use solution at elevated temperature allows a lower MEC for effective high-level disinfection.

CIDEX® OPA Concentrate Solution follows the intent of International Organization for Standardization recommendations (ISO-15883-4) for use of high-level disinfectants in AERs, which state that “discharge after a single use, during each cycle, is the preferred option.”⁴ Automatic endoscope reprocessor systems that deliver a single injection of high-level disinfectant for each cycle provide fresh disinfection solution every time and reduce the risk of cross-contamination. The ISO standard establishes performance standards for washer-disinfectors for better patient care and improved safety. As a result, meeting its recommendations should be an important criterion in evaluating disinfection systems.

Proven Efficacy

CIDEX® OPA Concentrate Solution has been tested extensively for germicidal efficacy using microorganisms from the American Type Culture Collection (ATCC), the Collection de L'Institut Pasteur (CIP), and the Trudeau Mycobacterial Culture Collection (TMC). The in-use solution (0.055% *ortho*-phthalaldehyde) is bactericidal, fungicidal, mycobactericidal (including tuberculocidal), sporicidal, and virucidal. The tests and results that led to these conclusions of efficacy are summarized below [data on file at ASP].

Bactericidal. The in-use solution of CIDEX® OPA Concentrate is bactericidal. The in-use solution was assessed against representative pathogens at 50° C for 5 minutes. Testing was done according to the Association of Analytical Chemists International (AOAC) Use-Dilutions Test methodology and the European standard NF EN 13727.

In the AOAC Use-Dilutions tests, all tested bacteria showed no growth, including:

- *Staphylococcus aureus* (ATCC 6538)
- *Salmonella choleraesuis* (ATCC 10708)
- *Pseudomonas aeruginosa* (ATCC 15442)
- Methicillin-resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)
- Vancomycin-resistant *Enterococcus faecalis* (VRE) (ATCC 51575)

In the NF EN 13727 tests, all organisms showed greater than 5-log reduction in colony forming units/mL, including:

- *Staphylococcus aureus* (CIP 4.83)
- *Enterococcus hirae* (CIP 58.55)
- *Pseudomonas aeruginosa* (CIP 103467)

Fungicidal. The in-use solution of CIDEX® OPA Concentrate is efficacious against *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans* when the fungi are exposed to the disinfectant at 50° C for 5 minutes. In the AOAC Fungicidal Activity of Disinfectants test, *T. mentagrophytes* (ATCC 9533) showed no growth after exposure to the in-use solution. In the European standard NF EN 14562 test, exposure to the in-use solution reduced colony formation by more than 4 log₁₀ for *A. niger* (ATCC 16404) and *C. albicans* (ATCC 10231).

Mycobactericidal. The in-use solution of CIDEX® OPA Concentrate is mycobactericidal when used as directed and also fits the U.S. Environmental Protection Agency (EPA) definition of tuberculocidal. In the quantitative suspension test endorsed by the EPA, exposure of *Mycobacterium bovis* BCG (TMC 1028) to CIDEX OPA Concentrate in-use solution at 50° C for 5 minutes caused greater than 6-log₁₀ reduction in the number of viable organisms.

Efficacy against mycobacteria also was tested according to two European standards. *Mycobacterium avium* (ATCC 15769) and *Mycobacterium terrae* (ATCC 15755) were exposed to the in-use solution at 50° C for 5 minutes. In tests consistent with European standard prEN 14563 (glass carriers) for both mycobacterial strains, exposure to disinfectant resulted in greater than 5-log reduction in viable organisms. In tests consistent with BS EN 14348, exposure resulted in greater than 6-log reduction of viable mycobacteria.

Virucidal. Results of the EPA Virucide Assay and a European standard assay showed that the in-use solution of CIDEX® OPA Concentrate is virucidal. The in-use solution at 50° C with an exposure time of 5 minutes passed the EPA test (passing grade, >3-log₁₀ reduction) for a virucide against all viruses tested, including:

- Adenovirus type 5
- Cytomegalovirus
- Herpes simplex type 1
- Human coronavirus
- Influenza A (Hong Kong)
- Rotavirus (strain WA)
- Poliovirus type 1 (Brunhilde strain)
- Coxsackie virus type B3
- Duck hepatitis B virus
- Herpes simplex type 2
- HIV type 1
- Rhinovirus type 37
- Vaccinia virus

Efficacy also was tested with a European standard using two viruses. At 50° C with an exposure time of 5 minutes, the in-use solution passed the European standard NF EN 14476 (defined as >4-log₁₀ reduction) for adenovirus type 5 and poliovirus type 1 (Sabin strain).

Sporicidal. Although high-level disinfectants for semi-critical medical devices are not required to kill all spores,³ laboratory testing has shown that the in-use solution of CIDEX® OPA Concentrate is sporicidal. For

example, it was tested at 50° C against spore forms of *Clostridium difficile* (ATCC 700792), achieving a 3.1 log₁₀ reduction in viable spores after 2 hours and a 5.6 log₁₀ reduction in 6 hours. In separate tests, at 50° C for 12 hours, the in-use solution achieved a reduction of 6.78 log₁₀ in viable *Clostridium sporogenes* spores and a 6.07 log₁₀ reduction in *Bacillus subtilis* spores.

Tests Simulating Clinical Use

While standard efficacy tests are critical for validation of germicides as high-level disinfectants, efficacy tests that simulate real use of the disinfectant also provide important information for clinicians and infection prevention professionals. Such simulated-use tests look at reduction of a test organism on a real medical device. Simulated-use tests with mycobacteria and organic soil (bovine serum) on a variety of endoscopes demonstrated the efficacy of the in-use solution of CIDEX® OPA Concentrate.

In a simulated-use test of the in-use solution, flexible endoscopes were contaminated with *Mycobacterium terrae* (ATCC 15755) suspended in 5% fetal bovine serum. Each endoscope carried approximately 1 x 10⁷ test organisms. The serum simulated organic soil that would be expected after clinical use of an endoscope. On all three types of endoscopes tested—bronchoscopes, duodenoscopes, and colonoscopes—5-minute exposure to the in-use solution of CIDEX OPA Concentrate at 50° C resulted in greater than 6.5-log₁₀ reduction in viable organisms.

Gentleness on Instruments

In addition to efficacy, a key consideration in selecting a high-level disinfectant for flexible endoscopes is materials compatibility, as damage to expensive, delicate instruments is costly in terms of repair and replacement costs. Damaged endoscopes sent out for repair also are unavailable for procedures, disrupting surgical schedules and requiring an increase in inventory of these expensive items.

CIDEX® OPA Concentrate Solution has been shown to be compatible with a wide range of materials, including temperature-sensitive materials used in flexible endoscopes (Table 1). CIDEX OPA Concentrate Solution offers

excellent materials compatibility when used in AER systems from ASP, reducing instrument damage and resulting repair costs for flexible endoscopes—critical issues for busy GI departments and endoscopy centers.

Table 1. Testing shows that CIDEX® OPA Concentrate Solution is compatible with a variety of materials used in medical devices and surgical instruments*

Metals	Plastics	Adhesives	Elastomers
Aluminum	Nylon	Epoxy	Buna-N rubber
Brass	Polyethylene		Silicone rubber
Copper	Polypropylene		Polyurethane
Stainless steel	Polycarbonate		Neoprene
	Composite polyethylene tubing		Viton rubber
	Polyvinylchloride		EPDM rubber
	Teflon		
	Polyacetal		
	Utem		

*Materials exposed continuously to CIDEX® OPA Concentrate Solution for 5 days at 55° C with no signs of deterioration.

Summary

Ensuring thorough high-level disinfection of flexible endoscopes is just one challenge facing busy endoscopy centers and GI departments. To improve consistency, reduce costs, and increase efficiency, many centers are turning to innovative automated endoscope reprocessors and high-level disinfectants from Advanced Sterilization Products. ASP's automatic endoscope reprocessor systems utilize CIDEX® OPA Concentrate Solution, a proven high-level disinfectant offering broad materials compatibility in a unique formulation that ensures fresh disinfectant for every endoscope. It also reduces the risk of cross-contamination and staff exposure to disinfectant and pathogens. CIDEX OPA Concentrate Solution is efficacious, gentle on instruments, and fast acting, allowing rapid turnaround of instruments. Together, they provide a consistent, high standard of care and allow healthcare professionals to allocate more time to patient-care activities. ■

References

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