



## Standards and Guidelines

### **Guideline for the Use of High-Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes**

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### Preface

Professional associations and regulatory agencies recognize high-level disinfection as the standard of care in reprocessing flexible endoscopes (American Society for Gastrointestinal Endoscopy ASGE, 2001). As of January 30, 2002, the Food and Drug Administration (FDA) has cleared nineteen products as sterilants and high-level disinfectants with general claims for reprocessing reusable medical and dental devices (FDA, 2002). Many high-level disinfectants/sterilants are distributed under different brand names, but contain the same chemical composition. The current FDA document has listed these products by brand name. It is beyond the scope of this document to review each individual product. Therefore, this guideline provides information about the properties of the main ingredients of these solutions, their safe and effective use and their compatibility with flexible endoscopes.

### Definition of Terms

For the purpose of this document, SGNA has adopted the following definitions:

**Endoscope** refers only to flexible gastrointestinal endoscopes.

**Low-level disinfection** refers to a process that can kill most bacteria, some viruses and some fungi, but it cannot be relied on to kill resistant organisms such as tubercle bacilli or bacterial spores (Rutala, 1996).

**High-level disinfection (HLD)** refers to the destruction of all microorganisms with the exception of high levels of bacterial spores (Rutala, 1996). **High-level disinfectant/sterilant** refers to a chemical germicide that has been cleared by the FDA as capable of destroying all microorganisms, including all bacterial spores. When used at a shorter exposure time it destroys all viruses, vegetative bacteria, fungi, mycobacterium and some, but not all, bacterial spores (Rutala, 1996).

**Material Safety Data Sheet (MSDS)** refers to a descriptive sheet that accompanies a chemical or chemical mixture, providing the identity of the material; physical hazards, such as flammability; acute and chronic health hazards associated with contact with or exposure to the compound.

**Minimum effective concentration (MEC)** refers to the lowest concentration of active ingredient necessary to meet the label claim of a reusable high-level disinfectant/sterilant.

**Mutagen** refers to a substance capable of inducing or accelerating changes in a gene or chromosome.

**Sterilant** refers to a chemical germicide that has been cleared by the FDA as capable of destroying all microorganisms, including all bacterial spores (Rutala, 1996).

**Sterile** refers to the state of being free from all living organisms.

**Sterilization** refers to a process that results in the complete elimination or destruction of all forms of microbial life. The Spaulding Classification identifies sterilization as the standard for medical devices that enter the vascular system or sterile tissue, such as biopsy forceps (Rutala, 1996).

**Teratogen** refers to an agent that increases the incidence of a congenital malformation.

**Threshold limit value ceiling (TLV-C)** refers to the airborne concentration of a substance that should not be exceeded during any part of the work experience (American Conference of Governmental Industrial Hygienists [ACGIH], 1998).

**Threshold limit value time-weighted average (TLV-TWA)** refers to the airborne concentration of a substance to which all workers may be exposed day after day without experiencing any adverse health effects (ACGIH, 1998).

**Use-life** refers to a statement by the manufacturer indicating the maximum number of days a reusable high-level disinfectant/sterilant might be effective.

## **Spaulding Classification for Medical Devices and Level of Disinfection (Block, 2001)**

Dr E. H. Spaulding devised a classification system that divided medical devices into categories based on the risk of infection involved with their use. This classification system is used by the FDA, the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists, and professional medical organizations to aid in determining the degree of disinfection or sterilization required for various medical devices. Spaulding defines three categories of medical devices and their associated level of disinfection or sterilization.

**Critical:** A device that enters normally sterile tissue or the vascular system. These devices should be sterilized.

**Semicritical:** A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices should receive at least high-level disinfection.

**Noncritical:** Devices that do not ordinarily touch the patient or touch only intact skin. These devices may be cleaned by low-level disinfection.

## **General Principles Common to the Use of All High Level Disinfectants and/or Sterilants**

### **Product Safety**

None of the chemicals addressed in this document is a carcinogen. Glutaraldehyde is neither a mutagen nor a teratogen (Union Carbide, 1995a). The Material Safety Data Sheet (MSDS) for peracetic acid lists information on mutagenicity, teratogenicity and reproductive toxicity as “not available” (STERIS, 2001). The MSDS for ortho-phthalaldehyde states the product is not reported to produce mutagenic, embryogenic, teratogenic or reproductive effects in humans (Advanced Sterilization Products, 2001).

It is imperative that healthcare workers who use any high-level disinfectant and/or sterilant be familiar with and have readily accessible the product/brand-specific MSDS for all chemicals used, follow Occupational Safety and Health Administration (OSHA) guidelines, and keep current with developments in products, protective equipment, and practice.

## Manual Cleaning

Meticulous manual cleaning of all instruments must precede exposure to any high-level disinfectant or sterilant (SGNA, 1997). Inadequate cleaning of instruments has been one factor cited in transmission of infection by flexible endoscopes. Studies demonstrate that appropriate cleaning reduces the number of microorganisms and organic load by 4 logs or 99.9% (Chu, 1998). This significantly reduces the organic and microbial challenge to the high-level disinfectant or sterilant. A detailed cleaning protocol for endoscopes is found in SGNA's *Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes* (2000). Endoscope manufacturers' guidelines should always be consulted for design features unique to a particular instrument.

Cleaning of endoscopes prior to chemical exposure includes purging the air/water channel, using enzymatic detergent solution for cleaning the exterior of the instrument, and brushing all valves and accessible channels. The endoscope must then be immersed in fresh enzymatic detergent solution, which is flushed through all channels. Some automated reprocessors provide for irrigation of enzymatic solution. If not, this step must be done manually prior to beginning the automated cycle.

## Determining Minimum Effective Concentration

Glutaraldehyde, 7.5% hydrogen peroxide, 0.08% peracetic acid/1% hydrogen peroxide and 0.55% ortho-phthalaldehyde are reusable products. The challenges of microbes and organic matter, dilution by rinse water and age of the chemical solution result in a gradual reduction of the effectiveness of reusable high-level disinfectant/sterilants. Reusable high-level disinfectant/sterilants must be changed whenever the MEC fails or the use life expires, whichever comes first. If additional chemical solution is added to an automated endoscope reprocessor (AER) or basin (if manually disinfected) the reuse life should be determined by the first use/activation of the original solution. The practice of "topping off" of the chemical does not extend the reuse life (ASGE, in press). The appropriate number of reuses of each of these products must be determined by testing that the solution is at or above its MEC. Use product-specific test strips. MEC should be monitored at least each day of use and more frequently as dictated by the number of endoscopes reprocessed (SGNA, 1997). Maintain a log of test results. [See Appendix A for a sample log.]

## Final Rinse/Alcohol Purge

Irrespective of the quality of the water used to rinse flexible endoscopes during manual or automated reprocessing (e.g., "clean" water, tap water, "fresh" water, rinse water labeled as "bacteria-free," or rinse water labeled as "sterile"), the entire endoscope must be dried, with each of its internal channels being flushed with 70% alcohol, followed by forced air drying, both between patient procedures and prior to storage. Storage of the endoscope in a dry and well ventilated environment in accordance with the endoscope manufacturer's instructions is important to prevent the colonization of bacteria and patient infection.

This practice of drying, when performed properly and in addition to thorough cleaning and high-level disinfection (or "sterilization") of the endoscope, eliminates the need to reprocess each endoscope before the first patient of the day. Compared to reprocessing, drying and properly storing the endoscope at the end of the day, there are no independent data that suggest reprocessing endoscopes in the morning of the next day before the first patient - an expensive and time-consuming process - reduces the risk of patient infection. Published data suggest that drying the endoscope is essential to prevent patient infection (Muscarella, L.F.,2001).

## Personal Protective Equipment

Use personal protective equipment when reprocessing endoscopes, as exposure to high-level disinfectants, sterilants and/or body fluids may occur. *Gowns, gloves and protective eyewear* are recommended when handling any high-level disinfectant/sterilant. *Gowns* should be impervious to fluid, have long sleeves that fit snugly around the wrist, and wrap to cover as much of the body as possible. Dispose of or launder gowns if they become wet or are exposed to contaminated material. Inspect *gloves* for tears or holes before use. Do not use an imperfect glove or reuse disposable gloves. Gloves should be long enough to extend up the arm to protect the forearm or clothing from splashes or seepage. To avoid cross-contamination, change gloves and wash hands whenever moving from a dirty to clean task or environment. *Eye and/or face protection* is necessary. Contact lenses are not sufficient eye protection. A face shield (or safety glasses in combination with a facemask allowing for ventilation) is recommended. Each reprocessing area must contain an eyewash station. The MSDS for each high-level disinfectant/sterilants recommends evaluation by a physician in the event of eye exposure. Do not use high filtration masks since they may actually trap vapors.

## Material Compatibility

Endoscopes and automated reproprocessors are composed of a variety of materials such as rubbers, plastics and metals that may be affected by ingredients in high-level disinfectants or sterilants. Consult manufacturers of endoscopes and reproprocessors for results of compatibility studies as part of the process of choosing a product. Incompatibility may result in changes in appearance and function of an endoscope. Use of a high-level disinfectant or sterilant for which a manufacturer has not issued a compatibility statement may void the instrument's warranty. Third-party repair companies may use different materials in replacement components than those of the original equipment manufacturer. If using the services of a third party for repairs, consult them for compatibility and warranty information. See Appendix B for a chart summarizing compatibility listing of endoscope manufacturers.

## Susceptibility of Resistant Organisms

Organisms such as gram-negative rods and gram-positive bacteria, which are frequent contaminants of gastrointestinal endoscopes (Chu, 1998), are susceptible to 2% glutaraldehyde, 0.2% peracetic acid, 7.5% hydrogen peroxide, and 0.08% peracetic acid/1% hydrogen peroxide. Other microorganisms of concern in gastroenterology settings, such as *Clostridium difficile*, *Helicobacter pylori*, Hepatitis C virus, Hepatitis B virus, Human immunodeficiency virus (HIV), Vancomycin-resistant enterococcus, Methicillin-resistant *Staphylococcus aureus*, and multi-drug-resistant tuberculosis are also sensitive to these products (APIC, 1996). It is not necessary to deviate from routine reprocessing protocols when exposure to such organisms is suspected, since to do so would constitute a "double standard" of care (Rutala, 1999).

Concern has been raised over possible endoscopic transmission of prions and other transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease, kuru, and bovine spongiform encephalopathy. There have been no reported cases of transmission of these agents by endoscopy. The World Health Organization (WHO, 1999) recommends that the infectivity level of the tissue contaminating the instrument should guide the decontamination of medical instruments. Saliva, gingival tissue, intestinal tissue, feces, and blood are classified as having no detectable infectivity and, for the purposes of infection control for these agents, are regarded as noninfectious (Rutala, 2001). A draft statement on TSE and endoscopes from the CDC concluded that current guidelines for cleaning and disinfection of the instruments need not be changed (WHO, 1999).

## Glutaraldehyde

Glutaraldehyde has been used for more than 30 years in many health care settings for high-level disinfection and cold sterilization. It is the most widely used high-level disinfectant/sterilant for reprocessing gastrointestinal endoscopes. Glutaraldehyde products are marketed under a variety of brand names and are available in a variety of concentrations, with and without surfactants. Glutaraldehyde has excellent biocidal activity, is active in the presence of organic matter and is non-corrosive to metals, rubbers and plastics (APIC, 1996). Glutaraldehyde may be used in manual or automated reprocessing protocols. Olympus, Pentax and Fujinon list glutaraldehyde as compatible with their endoscopes. Glutaraldehyde is compatible with automated reproprocessors except STERIS SYSTEM 1.

In 1995, SGNA, in collaboration with the American Society for Gastrointestinal Endoscopy (ASGE), the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), and the Association for Professionals in Infection Control and Epidemiology (APIC) adopted the position, based on scientific data, that after meticulous manual cleaning, high-level disinfection is achievable with a 20 minute exposure at 20°C (room temperature) in a 2% glutaraldehyde solution which does not contain surfactant and which tests above its minimum effective concentration (ASGE, 1996). These conditions may not be extended to other glutaraldehyde solutions. This recommendation differs from the label claims on 2% glutaraldehyde stating a 45-minute exposure at 25°C for HLD because the current federal labeling regulation assumes no cleaning of the medical device prior to chemical exposure.

There are products that can achieve high-level disinfection with a shorter exposure time but require a higher temperature. An example of this is Rapicide™. Manufacturers' instructions must be followed for temperature and disinfection time.

Glutaraldehyde solutions range in concentration from 2.4 – 3.4% and have varied maximum use lives. For example, the maximum use life of an alkaline (activated) 2% glutaraldehyde without surfactants is 14 days. The actual use life of any reusable HLD/sterilant must be determined by testing for MEC with product-specific test strips. Labeling regulations require the manufacturer to place the MEC on the container. For example, test strips for 2.4% glutaraldehyde products are constructed to show failure when the concentration drops below 1.5% (Advanced Sterilization, 1999).

Glutaraldehyde is an irritant and some individuals develop acute sensitivities (CDC, 2001). These sensitivities may be displayed as itching of the skin with slight redness, to redness and swelling or yellowing of the skin with prolonged exposure, or irritation to eyes and nasal membranes, headache, coughing, sneezing, and asthma-like symptoms. Glutaraldehyde can be absorbed by inhalation, ingestion and through the skin. It has a detectable odor at 0.04 parts per million volume (ppmv) and is irritating to skin and mucous membranes at 0.3 ppmv. Vapors are released whenever solutions are disturbed and the surface tension is broken. Mixing, adding and removing equipment, or disposing of a glutaraldehyde solution can cause a break in the surface tension (Notarianni, 1992). Whenever the glutaraldehyde solution is not being accessed, it should be covered with a tight-fitting lid.

Provide adequate ventilation in areas where glutaraldehyde is in use. Ventilation systems should be installed by certified heating, ventilation and air conditioning (HVAC) professionals in order to ensure that the system designed for removal of glutaraldehyde does not interfere with other HVAC systems in the facility (Burkhart, 1991). Adequate ventilation, as described by AAMI (1996) and Burkhart (1991), includes the following:

- Room large enough to ensure adequate dilution of vapors.
- 10 air exchanges per hour to allow volume flow rate of air moving through the room to be at least 1.0 to 2.0 cubic feet per minute per square foot of floor area (Burton, 1994).

- Exhaust located at the source of the discharge of vapors (pulling vapors away from the user's breathing zone). This can be done by placing the exhaust fan at foot level or on a countertop and venting the vapors to the outside.
- Fresh air return entering at ceiling level across the room from the exhaust vents.
- Routine maintenance and surveillance of the system to ensure continued proper functioning.
- Elimination of cross-draft effects.
- Care should be taken to ensure that the discharge of the vapors is sufficiently removed from windows, outside air intakes or other such openings to prevent reentry of the discharged air. Air must not be recirculated.

In areas where local exhaust ventilation systems are not in place, use ductless fume ventilation devices that contain filters to absorb glutaraldehyde vapors from the air. These hoods should achieve a face velocity of at least 100 feet per minute with the airflow directed toward the back of the hood, away from the user's breathing zone (Burkhart, 1991).

In 1998, the American Conference of Governmental Industrial Hygienists (ACGIH) lowered its recommended TLV-C from 0.2ppm to 0.05ppm. Monitor glutaraldehyde vapors if there is reason to believe the TLV-C exceeds the recommendation, if an employee exhibits symptoms of overexposure, or following any corrective action taken to lower vapor levels. Devices are available for area monitoring and for monitoring of an employee's breathing zone. Follow manufacturer's directions to ensure that the device is used in a manner that will achieve the most accurate analysis. Monitor at the peak time of exposure, such as when fresh solutions are being mixed and transferred to containers.

Changing latex gloves every 15 minutes during periods of glutaraldehyde exposure or using double gloves provides up to a four-fold increase in permeation time compared with single latex gloves. One hundred percent nitrile rubber or 100% butyl rubber gloves are recommended for the best protection from glutaraldehyde. Neoprene and polyvinyl chloride (PVC) gloves are not recommended as these materials absorb and retain glutaraldehyde (Jordan, 1995).

Glutaraldehyde spills small enough not to cause tearing of the eyes and/or respiratory discomfort can be cleaned up with a mop, sponge or towel. Discard the saturated item in a tightly sealed biohazard bag. Rinse surfaces thoroughly with water. Large spills may require neutralization with sodium bisulfite or 2% dibasic ammonium phosphate (Metrex Research Corporation, 2001). Have one of these chemicals available wherever glutaraldehyde is used. Be familiar with the MSDS recommendations for spill or leak procedures and consult with the institution's Safety Officer to prepare a plan for handling spills.

In most states, glutaraldehyde solutions that have failed MEC tests can be discarded down the drain and flushed with large amounts of water. Triple-rinse empty containers from freshly activated solutions with water prior to disposal. Consult state and local regulations for possible differences in disposal requirements.

## **0.2% Peracetic Acid**

Peracetic acid is part of the family of peroxygen compounds. The STERIS Corporation has marketed STERIS 20 Sterilant Concentrate™, a 35% peroxyacetic acid concentrate, for use in the STERIS SYSTEM 1 since 1987. STERIS SYSTEM 1 is FDA-cleared as a liquid chemical sterilization processor for medical devices. The processor dilutes and mixes the Steris 20 sterilant concentrate to its final concentration of 0.2%

peracetic acid with a neutral pH, which is sporocidal at 50°C. The processing cycle is approximately 30 minutes and reaches temperatures of 50° -56° during exposure time (STERIS Corporation, 1997a). The STERIS SYSTEM 1 has become widely used for reprocessing of flexible gastrointestinal endoscopes. Instruments processed with 0.2% peracetic acid must be handled and stored in a sterile manner upon removal from the STERIS SYSTEM 1 in order to be considered sterile at the point of next use.

A concentration of 0.2% peracetic acid is rapidly active against all microorganisms including bacterial spores, and is effective in the presence of organic matter. It is only available in the United States in conjunction with the automated STERIS SYSTEM 1. A chemical indicator for each cycle measures the ionic strength of buffering agents. A biological indicator is available, but may not be suitable for routine monitoring of liquid sterilants. Two criticisms are that the indicator cannot be placed in the least accessible location of an endoscope, and that liquid sterilants are thought to cause spores to wash off the indicator strip (Rutala, 1999). Fuselier (1997) published a study comparing STERIS SYSTEM 1 and manual reprocessing with a 2% glutaraldehyde solution for flexible cystoscopes. They concluded that clinical outcomes were the same.

When handled properly, the peracetic acid used in the STERIS SYSTEM 1 is self-contained, circulated around and through the endoscope via channel connectors, and discarded down the drain. The processor then rinses the instrument with large amounts of filtered water. STERIS SYSTEM 1 does not have the capability to circulate enzymatic detergent solutions.

Pentax and Fujinon list the STERIS SYSTEM 1 as compatible with its endoscopes. Olympus does not list STERIS SYSTEM 1 as compatible with its endoscopes.

Cartons of the peracetic acid concentrate should be stored upright in a cool, dry area (<86°F). They have a shelf life stability of six months. Care should be taken not to damage the STERIS 20 Concentrate™ sealed container. The concentrate may cause irritation of the nose, throat and lungs, and is corrosive to the eye and skin, potentially causing irreversible eye damage or severe burns. General or local exhaust ventilation systems are adequate. In the event of a spill or leak of the concentrate, increase ventilation and shut off ignition sources. Wearing protective equipment, flush spilled material with large quantities of water (at least 20 times the volume spilled). Consult the STERIS 20 Concentrate™ MSDS for information to assist in cleaning up a spill. Once diluted to 0.2%, peracetic acid is not considered a hazardous waste and can be safely discarded down the drain (STERIS Corporation, 1997b).

## **7.5% Hydrogen Peroxide**

Although the FDA has approved products containing 7.5% Hydrogen Peroxide as a high-level disinfectant/sterilant, it has not been found to be compatible with flexible gastrointestinal endoscopes manufactured by Olympus, Pentax or Fujinon.

## **0.08% Peracetic Acid/1% Hydrogen Peroxide**

Although the FDA has approved products containing 0.08% Peracetic Acid/1% Hydrogen Peroxide as a high-level disinfectant/sterilant, it has not been found to be compatible with flexible gastrointestinal endoscopes manufactured by Olympus, Pentax or Fujinon.

## 0.55% Ortho-phthalaldehyde

In late 1999, 0.55% ortho-phthalaldehyde (OPA) was introduced to market as CIDEX® OPA SOLUTION. It is cleared by the FDA as a high-level disinfectant at 20°C at an immersion time of 12 minutes (Advanced Sterilization Products, 1999). CIDEX® OPA is not intended nor is it cleared for use as a sterilant. No mixing or activation is required. A hospital-based study of ortho-phthalaldehyde found it to be effective in eradicating vegetative bacteria, fungi and parasites from bronchoscopes, gastroscopes and colonoscopes (Alfa and Sitter, 1994). Two studies have assessed its tuberculocidal properties. One found it to be more rapidly tuberculocidal than glutaraldehyde in the laboratory setting (Gregory, 1999). The other suggests that OPA is effective against glutaraldehyde resistant mycobacteria (Walsh1999).

CIDEX® OPA is a reusable product with a maximum use life of 14 days. Like all other reusable products, its actual use life must be determined by testing that the solution remains at or above its minimum effective concentration of 0.3%. Studies indicate that OPA may remain above its MEC despite reuse and dilution better than glutaraldehyde (Gregory, 1999) Like other high-level disinfectants, meticulous manual cleaning of medical devices must precede exposure to this product. CIDEX® OPA may be used in manual or automated reprocessing protocols. Check with manufacturers of automated reprocessors for specific compatibility statements.

Ortho-phthalaldehyde has a wide range of material compatibility. Pentax and Fujinon list it as a compatible product. Olympus lists it as compatible with all endoscopes except the OSF and OSF-2.

CIDEX® OPA is a clear blue solution with little odor. It is a potential irritant of eyes, skin, nose and other tissues resulting in symptoms such as stinging, excessive tearing, coughing and sneezing. It is a potential skin and respiratory sensitizer that may cause dermatitis with prolonged or repeated contact and may aggravate pre-existing bronchitis or asthma. In addition, the product stains proteins on surfaces to gray/black.

Small spills may be cleaned up with a damp sponge or absorbent pad. Larger spills should be deactivated with 25 grams of glycine (free base) powder per gallon over 5 minutes. See the MSDS for specific control measures. Triple-rinse empty containers with water prior to disposal. Spent solutions of ortho-phthalaldehyde may be disposed of down the drain unless prohibited by state and local regulations.

## Summary

Products containing glutaraldehyde, 0.2% peracetic acid, 7.5% hydrogen peroxide, 0.08% peracetic acid/1% hydrogen peroxide, and 0.55% ortho-phthalaldehyde are cleared by the FDA as high-level disinfectants/sterilants. Only glutaraldehyde, 0.2% peracetic acid, and 0.55% ortho-phthalaldehyde are compatible with flexible gastrointestinal endoscopes. Each product has advantages and disadvantages. All require adherence to published reprocessing protocols in order to maintain the integrity of equipment while providing the public with endoscopic instruments that are safe and effective. All chemicals must be handled with respect. Selection of a product must be weighed against the needs of a particular setting, taking into consideration factors such as compatibility, toxicity, environmental controls and cost.

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**Appendix A: Sample MEC Log**

**Facility Name**

**MINIMUM EFFECTIVE CONCENTRATION LOG FOR**  
**: \_\_\_\_\_**

**Pan/Reprocessor: \_\_\_\_\_**

DATE	# USES	PASS/FAIL MEC	INITIALS	COMMENT

**EXAMPLE:**

**Smith Endoscopy Center**

**MINIMUM EFFECTIVE CONCENTRATION LOG FOR : 2.4%  
 GLUTARALDEHYDE**

**Pan/Reprocessor: B**

DATE	# USES	PASS/FAIL MEC	INITIALS	COMMENT
2/1/99	16	Pass	MJ	Last changed on 1/26/99
2/2/99	24	Pass	MJ	
2/3/99	31	Pass	MJ	
2/4/99	38	Pass	MJ	
2/4/99	39	Pass	MJ	
2/4/99	40	Pass	MJ	
2/4/99	41	Fail	MJ	Changed 11am 2/4/99
2/5/99	3	Pass	MJ	

**Appendix B: HLD Compatibility with Endoscopes**

(Data provided by endoscope manufacturers)

	Olympus	Pentax	<b>Fujinon</b>
Glutaraldehyde	C	C	C
0.2% Peracetic Acid	NC	C	C
<b>7.5% Hydrogen peroxide</b>	NC	NC	NC
0.08% peracetic acid/1% hydrogen peroxide	NC	NC	NC
0.55% Ortho-phthalaldehyde	C	C	C

C = company lists as compatible

NC = company does not list as compatible

## **Appendix C**

The FDA's most recent list of Sterilants and High Level Disinfectants cleared in a 510(k) with General Claims for Processing Reusable Medical and Dental Devices can be accessed at on the Internet at

<http://www.fda.gov/cdrh/ode/germlab.html>

or by calling FDA's Division of Dental, Infection Control and General Hospital Devices, ODE at 301/443-8879.