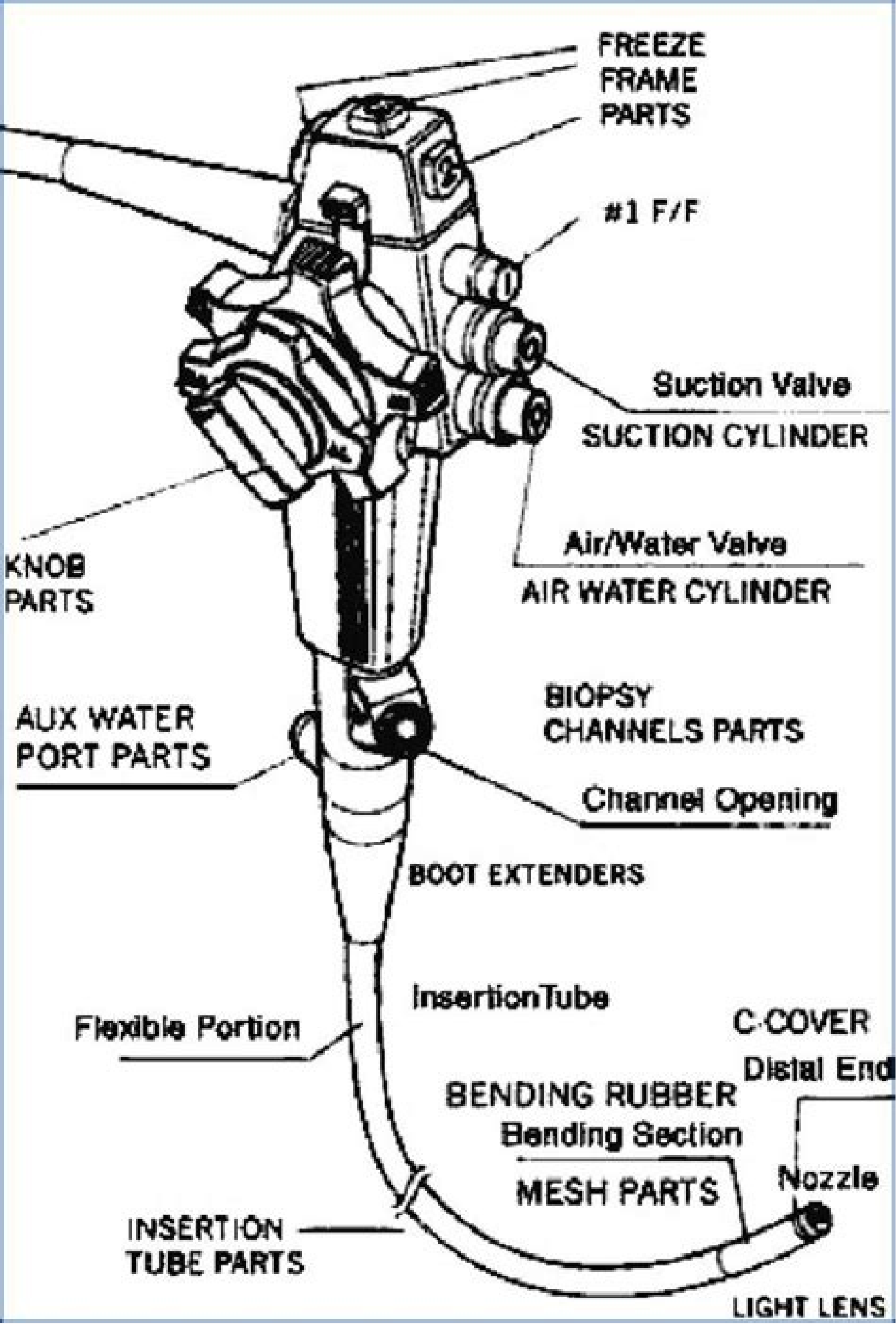


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Olympus endoscope cleaning guide. Olympus endoscope pre cleaning guide.

Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) In the healthcare setting, “alcohol” refers to two water-soluble chemical compounds—ethyl alcohol and isopropyl alcohol—that have generally underrated germicidal characteristics 482. FDA has not cleared any liquid chemical sterilant or high-level disinfectant with alcohol as the main active ingredient. These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and virucidal but do not destroy bacterial spores. Their cidal activity drops sharply when diluted below 50% concentration, and the optimum bactericidal concentration is 60%-90% solutions in water (volume/volume) 483, 484. Top of Page Mode of Action. The most feasible explanation for the antimicrobial action of alcohol is denaturation of proteins. This mechanism is supported by the observation that absolute ethyl alcohol, a dehydrating agent, is less bactericidal than mixtures of alcohol and water because proteins are denatured more quickly in the presence of water 484, 485. Protein denaturation also is consistent with observations that alcohol destroys the dehydrogenases of *Escherichia coli* 486, and that ethyl alcohol increases the lag phase of *Enterobacter aerogenes* 487 and that the lag phase effect could be reversed by adding certain amino acids. The bacteriostatic action was believed caused by inhibition of the production of metabolites essential for rapid cell division. Top of Page Microbicidal Activity. Methyl alcohol (methanol) has the weakest bactericidal action of the alcohols and thus seldom is used in healthcare 488. The bactericidal activity of various concentrations of ethyl alcohol (ethanol) was examined against a variety of microorganisms in exposure periods ranging from 10 seconds to 1 hour 483. *Pseudomonas aeruginosa* was killed in 10 seconds by all concentrations of ethanol from 30% to 100% (v/v), and *Serratia marcescens*, *E. coli* and *Salmonella typhosa* were killed in 10 seconds by all concentrations of ethanol from 40% to 100%. The gram-positive organisms *Staphylococcus aureus* and *Streptococcus pyogenes* were slightly more resistant, being killed in 10 seconds by ethyl alcohol concentrations of 60%-95%. Isopropyl alcohol (isopropanol) was slightly more bactericidal than ethyl alcohol for *E. coli* and *S. aureus* 489. Top of Page Ethyl alcohol, at concentrations of 60%-80%, is a potent virucidal agent inactivating all of the lipophilic viruses (e.g., herpes, vaccinia, and influenza virus) and many hydrophilic viruses (e.g., adenovirus, enterovirus, rhinovirus, and rotaviruses but not hepatitis A virus (HAV) 58 or poliovirus) 49. Isopropyl alcohol is not active against the nonlipid enteroviruses but is fully active against the lipid viruses 72. Studies also have demonstrated the ability of ethyl and isopropyl alcohol to inactivate the hepatitis B virus(HBV) 224, 225 and the herpes virus, 490 and ethyl alcohol to inactivate human immunodeficiency virus (HIV) 227, rotavirus, echovirus, and astrovirus 491. Top of Page In tests of the effect of ethyl alcohol against *M. tuberculosis*, 95% ethanol killed the tubercle bacilli in sputum or water suspension within 15 seconds 492. In 1964, Spaulding stated that alcohols were the germicide of choice for tuberculocidal activity, and they should be the standard by which all other tuberculocides are compared. For example, he compared the tuberculocidal activity of iodophor (450 ppm), a substituted phenol (3%), and isopropanol (70%/volume) using the mucin-loop test (106 M. tuberculosis per loop) and determined the contact times needed for complete destruction were 120-180 minutes, 45-60 minutes, and 5 minutes, respectively. The mucin-loop test is a severe test developed to produce long survival times. Thus, these figures should not be extrapolated to the exposure times needed when these germicides are used on medical or surgical material 482. Ethyl alcohol (70%) was the most effective concentration for killing the tissue phase of *Cryptococcus neoformans*, *Blastomyces dermatitidis*, *Coccidioides immitis*, and *Histoplasma capsulatum* and the culture phases of the latter three organisms aerosolized onto various surfaces. The culture phase was more resistant to the action of ethyl alcohol and required about 20 minutes to disinfect the contaminated surface, compared with 500 ppm). Inactivation by organic matter, discoloring or “bleaching” of fabrics, release of toxic chlorine gas when mixed with ammonia or acid (e.g., household cleaning agents) 523-525, and relative stability 327. The microbicidal activity of chlorine is attributed largely to undissociated hypochlorous acid (HOCl). The dissociation of HOCl to the less microbicidal form (hypochlorite ion OCl-) depends on pH. The disinfecting efficacy of chlorine decreases with an increase in pH that parallels the conversion of undissociated HOCl to OCl- 329, 526. A potential hazard is production of the carcinogen bis(chloromethyl) ether when hypochlorite solutions contact formaldehyde 527 and the production of the animal carcinogen trihalomethane when hot water is hyperchlorinated 528. After reviewing environmental fate and ecologic data, EPA has determined the currently registered uses of hypochlorites will not result in unreasonable adverse effects to the environment 529. Top of Page Alternative compounds that release chlorine and are used in the health-care setting include demand-release chlorine dioxide, sodium dichloroisocyanurate, and chloramine-T. The advantage of these compounds over the hypochlorites is that they retain chlorine longer and so exert a more prolonged bactericidal effect. Sodium dichloroisocyanurate tablets are stable, and for two reasons, the microbicidal activity of solutions prepared from sodium dichloroisocyanurate tablets might be greater than that of sodium hypochlorite solutions containing the same total available chlorine. First, with sodium dichloroisocyanurate, only 50% of the total available chlorine is free (HOCl and OCl-), whereas the remainder is combined (monochloroisocyanurate or dichloroisocyanurate), and as free available chlorine is used up, the latter is released to restore the equilibrium. Second, solutions of sodium dichloroisocyanurate are acidic, whereas sodium hypochlorite solutions are alkaline, and the more microbicidal type of chlorine (HOCl) is believed to predominate 530-533. Chlorine dioxide-based disinfectants are prepared fresh as required by mixing the two components (base solution [citric acid with preservatives and corrosion inhibitors] and the activator solution [sodium chlorite]). In vitro suspension tests showed that solutions containing about 140 ppm chlorine dioxide achieved a reduction factor exceeding 106 of *S. aureus* in 1 minute and of *Bacillus atrophaeus* spores in 2.5 minutes in the presence of 3 g/L bovine albumin. The potential for damaging equipment requires consideration because long-term use can damage the outer plastic coat of the insertion tube 534. In another study, chlorine dioxide solutions at either 600 ppm or 30 ppm killed *Mycobacterium avium*-intracellular within 60 seconds after contact but contamination by organic material significantly affected the microbicidal properties535. Top of Page The microbicidal activity of a new disinfectant, “superoxidized water,” has been examined The concept of electrolyzing saline to create a disinfectant or antiseptics is appealing because the basic materials of saline and electricity are inexpensive and the end product (i.e., water) does not damage the environment. The main products of this water are hypochlorous acid (e.g., at a concentration of about 144 mg/L) and chlorine. As with any germicide, the antimicrobial activity of superoxidized water is strongly affected by the concentration of the active ingredient (available free chlorine) 536. One manufacturer generates the disinfectant at the point of use by passing a saline solution over coated titanium electrodes at 9 amps. The product generated has a pH of 5.0-6.5 and an oxidation-reduction potential (redox) of >950 mV. Although superoxidized water is intended to be generated fresh at the point of use, when tested under clean conditions the disinfectant was effective within 5 minutes when 48 hours old 537. Unfortunately, the equipment required to produce the product can be expensive because parameters such as pH, current, and redox potential must be closely monitored. The solution is nontoxic to biologic tissues. Although the United Kingdom manufacturer claims the solution is noncorrosive and nondamaging to endoscopes and processing equipment, one flexible endoscope manufacturer (Olympus Key-Med, United Kingdom) has voided the warranty on the endoscopes if superoxidized water is used to disinfect them 538. As with any germicide formulation, the user should check with the device manufacturer for compatibility with the germicide. Additional studies are needed to determine whether this solution could be used as an alternative to other disinfectants or antiseptics for hand washing, skin antiseptics, room cleaning, or equipment disinfection (e.g., endoscopes, dialyzers) 400, 539, 540. In October 2002, the FDA cleared superoxidized water as a high-level disinfectant (FDA, personal communication, September 18, 2002). Top of Page Mode of Action. The exact mechanism by which free chlorine destroys microorganisms has not been elucidated. Inactivation by chlorine can result from a number of factors: oxidation of sulfhydryl enzymes and amino acids; ring chlorination of amino acids; loss of intracellular contents; decreased uptake of nutrients; inhibition of protein synthesis; decreased oxygen uptake; oxidation of respiratory components; decreased adenosine triphosphate production; breaks in DNA; and depressed DNA synthesis 329, 347. The actual microbicidal mechanism of chlorine might involve a combination of these factors or the effect of chlorine on critical sites 347. Top of Page Microbicidal Activity. Low concentrations of free available chlorine (e.g., HOCl, OCl-, and elemental chlorine-Cl2) have a biocidal effect on mycoplasma (25 ppm) and vegetative bacteria (6 log10 reduction in 5 minutes) and virucidal (5 log10 reduction in 5 minutes) 663. Synergistic sporicidal effects were observed when spores were exposed to a combination of hydrogen peroxide (5.9%-23.6%) and peracetic acid 664. Other studies demonstrated the antiviral activity of hydrogen peroxide against rhinovirus 665. The time required for inactivating three serotypes of rhinovirus using a 3% hydrogen peroxide solution was 6-8 minutes; this time increased with decreasing concentrations (18-20 minutes at 1.5%, 50-60 minutes at 0.75%). Top of Page Concentrations of hydrogen peroxide from 6% to 25% show promise as chemical sterilants. The product marketed as a sterilant is a premixed, ready-to-use chemical that contains 7.5% hydrogen peroxide and 0.85% phosphoric acid (to maintain a low pH) 69. The mycobactericidal activity of 7.5% hydrogen peroxide has been corroborated in a study showing the inactivation of >105 multidrug-resistant *M. tuberculosis* after a 10-minute exposure 666. Thirty minutes were required for >99.9% inactivation of poliovirus and HAV 667. Three percent and 6% hydrogen peroxide were unable to inactivate HAV in 1 minute in a carrier test 58. When the effectiveness of 7.5% hydrogen peroxide at 10 minutes was compared with 2% alkaline glutaraldehyde at 20 minutes in manual disinfection of endoscopes, no significant difference in germicidal activity was observed 668.). No complaints were received from the nursing or medical staff regarding odor or toxicity. In one study, 6% hydrogen peroxide (unused product was 7.5%) was more effective in the high-level disinfection of flexible endoscopes than was the 2% glutaraldehyde solution 456. A new, rapid-acting 13.4% hydrogen peroxide formulation (that is not yet FDA-cleared) has demonstrated sporicidal, mycobactericidal, fungicidal, and virucidal efficacy. Manufacturer data demonstrate that this solution sterilizes in 30 minutes and provides high-level disinfection in 5 minutes669. This product has not been used long enough to evaluate material compatibility to endoscopes and other semicritical devices, and further assessment by instrument manufacturers is needed. Top of Page Under normal conditions, hydrogen peroxide is extremely stable when properly stored (e.g., in dark containers). The decomposition or loss of potency in small containers is less than 2% per year at ambient temperatures 670. Top of Page Uses. Commercially available 3% hydrogen peroxide is a stable and effective disinfectant when used on inanimate surfaces. It has been used in concentrations from 3% to 6% for disinfecting soft contact lenses (e.g.,

for 2-3 hrs) 653, 671, 672, tonometer bipisms 513, ventilators 673, fabrics 397, and endoscopes 456. Hydrogen peroxide was effective in spot-disinfecting fabrics in patients' rooms 397. Corneal damage from a hydrogen peroxide-soaked tonometer tip that was not properly rinsed has been reported 674. Hydrogen peroxide also has been used to remove debris from an attempt to eliminate the bag as a source of bladder bacteria and environmental contamination 675. Although the instillation of hydrogen peroxide into the bag reduced microbial contamination of the bag, this procedure did not reduce the incidence of catheter-associated bacteremia 675. Top of Page A chemical disinfectant pseudomonas colitis 8% hydrogen peroxide or a 2% glutaraldehyde has been reported 621. An epidemic of pseudomonas like enterocolitis in seven patients in a gastrointestinal endoscopy unit has been associated with the inadequate rinsing of 3% hydrogen peroxide from the endoscope 676.

Top of Page As with other chemical sterilants, dilution of the hydrogen peroxide must be monitored by regularly testing the minimum effective concentration (i.e., 0.5%-6.0%). Compatibility testing by Olympus America of the 7.5% hydrogen peroxide found both cosmetic changes (e.g., discoloration of black anodized metal finishes) 69 and functional changes with the tested endoscopes (Olympus, written communication, October 15, 1999). Top of Page Iodophors Overview. Iodophor solutions or tinctures long have been used by health professionals primarily as antiseptics on skin or tissue. Iodophors, on the other hand, have been used both as antiseptics and disinfectants. FDA has not cleared any liquid chemical sterilant or a compound of disinfected with iodophors as the main active ingredient. An iodophor is a combination of iodine and a solubilizing agent or carrier; the resulting complex provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution. The best-known and most widely used iodophor is povidone-iodine, a high-level disinfectant based on polyvinylpyrrolidone with iodine. This product and other iodophors retain the germicidal efficacy of iodine but unlike iodine generally are nonstaining and relatively free of toxicity and irritation 677, 678. Top of Page Several reports that documented intrinsic microbial contamination of antiseptic formulations of povidone-iodine and poloxamer-iodine 679-681 caused a reappraisal of the chemistry and use of iodophors 682. "Free" iodine (I₂) contributes to the bactericidal activity of iodophors and dilutions of iodophors demonstrate more rapid bactericidal action than does a full-strength povidone-iodine solution. The reason for the observation that dilution increases bactericidal activity is unclear, but dilution of povidone-iodine might weaken the iodine linkage to the carrier polymer with an accompanying increase of free iodine in solution 680. Therefore, iodophors must be diluted according to the manufacturers' directions to achieve antimicrobial activity. Top of Page Mode of Action. Iodine can penetrate the cell wall of microorganisms quickly, and the lethal effects are believed to result from disruption of protein and nucleic acid structure and synthesis. Top of Page Microbicidal Activity. Published reports on the in vitro antimicrobial efficacy of iodophors demonstrate that iodophors are bactericidal, mycobactericidal, and virucidal but can be ineffective against pseudomonas aeruginosa 683. In vivo studies have demonstrated that adequate rinsing of 3% hydrogen peroxide from the endoscope after use is essential to prevent infection 684. Iodophors are also effective against spores 685. 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