

# “Guidelines for cleaning and disinfecting endoscopes” Second edition

Japanese Gastroenterological Endoscopy Technicians Society

Safety Management Committee Edition

(March 2004)



Newsletter No. 32 Supplementary Volume

Japanese Gastroenterological Endoscopy Technicians Society

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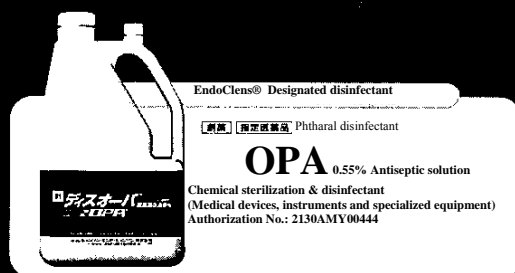
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## “Guidelines for cleaning and disinfecting endoscopes” Second edition

Japanese Gastroenterological Endoscopy Technicians Society Safety Management Committee

### I. Introduction

7 years have passed since the Japanese Gastroenterological Endoscopy Technicians Society first unveiled the Guidelines in 1996. Recently, infection control techniques have undergone a significant transformation. As a result, the committee has made partial revisions. Over the last several years, since new disinfectants have made an appearance with improvements and reduced processing times for cleaners, purifiers, endoscopic devices and treatment tools, there were sections in the guidelines that were far removed from the current conditions and were therefore revised.

The guidelines are meant for medical practices that are related to endoscopy. The difficulties concerning infection control many times involves things that cannot be seen or actual infections that are not immediately recognized. There exist parts to these problems that even healthcare personnel themselves do not fully understand. However, healthcare personnel have a major responsibility for preventing infection for examinations and treatment.

#### Disclaimer

These guidelines were created in order to recommend effective methods that are validated based on the latest evidence. However, it is difficult to predict all new infection risks and rising pathogenic microorganisms, and in addition, current recommendations may also no longer be applicable or necessary in the future.

For these reasons, infection control is complicated and changes over the course of time, and as a result, there are inherent limitations for all that is covered with these guidelines. Accordingly, said Committee shall not be responsible even if a detrimental or unfavorable event should occur despite executing these guidelines. In any case, they shall recommend what can be done within the current scope of available and executable conditions.

### II. Protection from infection

#### 1. Infection and Infectious disease

An infection<sup>1)</sup> is defined as a microorganism that settles in the host's biological surface, internally or inside the tissue, then proliferates and shows an adverse effect. However, even if microorganisms settle

and proliferate, it does not necessarily mean the host will show a pathological condition. For example, normal bacteria flora on the skin and mucous membranes function to defend against infection stopping the invasion of pathogenic bacteria and its proliferation. In addition, the conditions of an infectious disease are represented and shown by chills and high fever and the distinctive clinical symptoms of the bacteria.

#### 2. Endogenous infection and extrinsic infection

An endogenous infection (self-infection) is caused by the microorganisms, that are normally present within the host, deteriorating the host's body conditions (nutritional state, immune strength, invasion, aging). Surgical site infection is a bacterial infection from inside the intestine or the skin after gastrointestinal tract surgery. And there have been reports of cholangitis caused by the imaging of an obstructed bile duct in an endoscopy and of aspiration pneumonia caused by intraoral microorganisms when using sedatives.

On the other hand, an extrinsic infection (cross infection) refers to a case where the pathogen invades and infects from outside the host body (i.e., infection caused by an endoscope).

#### 3. Reaching infection

For infection, the following 6 factors must all be put together<sup>2)</sup>.

- 1) Pathogen (bacteria, virus, fungus, protozoa, prion)
- 2) Reservoir (Places that microorganisms inhabit: People, animals, instruments)
- 3) Exit point from reservoir (Airway: influenza; Digestive tract: dysentery; Endoscope: *Helicobacter pylori*)
- 4) Infection route a) air-borne infection: measles, chicken pox, tuberculosis b) droplet infection: influenza, rubella and others c) contact infection: MRSA, *Escherichia coli* O157 and others
- 5) Portal of entry for susceptible host: digestive tract, trachea, eyes, skin wound and others
- 6) Susceptible host: person

#### 4. Principles for infection control

In order to prevent the development of infection, one of the 6 factors must be removed. Among them, the simplest and most effective method is blocking the infection route. As a strategy for that, standard precautions<sup>3)</sup> and Spaulding classifications<sup>4)</sup> are essential.

#### 1) Standard precautions

As a method for infection control, fundamentally the most important idea is standard precautions. That idea concerns how to handle infectious things in skin wounds, mucous membranes, all blood and fluids, discharges (excluding perspiration) and excretions. In addition, this standard is not related to a presumed infectious state and can be applied to all patients.

One example is washing your hands with soap when touching something with your hands. When performing treatment, remove your gloves and wash your hands, and for more unclean conditions, use gloves, a face shield, mask and apron, etc. If the floor gets dirty, clean it. For needles, recapping is prohibited, use protective gear and equipment against needles and a box to dispose needles<sup>5)</sup>.

#### 2) Spaulding classification

Depending on the inherent risk to the body for medical equipment and materials used on the patient, under the Spaulding classification, the risk of infection is divided into 3 categories (critical, semi-critical and non-critical). For each level, the classification determines the appropriate disinfection method.

For example, biopsy forceps are inserted into a sterile site and therefore the infection risk is higher and the devices and material are classified as critical and must be sterilized. Also, since the endoscope comes into contact with mucous membrane, the risk of infection is lower and the devices and material are classified as semi-critical, and a high level disinfection applies. And finally, a cuff, which is used for taking blood pressure, touches the skin without wounds or injury on it is classified as a non-critical device or material with almost no risk of infection. Thus, it requires a low level disinfection or thorough cleaning (Table 1).

#### 5. Problems when checking for infectious diseases during cleaning and disinfection

There are no problems when standard precautions are taken for cleaning and disinfecting the endoscope, but it is not enough to simply check for contagious diseases before an endoscopy where the patient receives a negative result (-) for contagious diseases. And frequently inadequate processing or less time is spent for disinfection and cleaning due to the financial dimension. In addition, there is also the point of view that calls for a requirement to carry out an infectious disease examination ahead of time in order for the healthcare personnel to deal with any potential infection.

However, there is a problem as described below. Pathogenic microorganisms that can be checked with this method are limited to HBV and HC, etc., and in contrast Human Immunodeficiency Virus (HIV) and *Helicobacter pylori* (*H. pylori*) checks are not conducted. In addition, even if the exam result is negative, there still exists a possibility for infection because of the window period for the virus to discharge and cause an infection.

The goal of the infectious disease check, not just limited to HIV, must be explained to the patient and it requires patient consent. Furthermore, cleaning and disinfection expenses are less than those for the conducting an infectious disease check. And, if an infection were to occur while using an inadequate and inappropriate treatment method, one cannot evade the significant social and economic losses that will ensue.

#### III. Infection related to gastroenterological endoscopy

The resistance against disinfectants for infections that occur caused by various microorganisms varies depending on the type of microorganism (Table 2).

##### 1. Bacteria

In the transmission of infectious diseases due to bacteria, such as *Salmonella* spp., *Escherichia coli*, *Pseudomonas*, *Klebsiella*, *Enterobacter* spp., *Serratia marcescens*, *H. pylori*, etc., gram-negative bacillus is often transmitted.

##### 1) *Salmonella*

There are no endoscopic related infection reports in Japan, but the most abundant endoscopic infection transmission reports are for infections historically caused by *Salmonella* in overseas cases. In past *Salmonella* infection cases, infection has occurred due to inadequate endoscopic cleaning and disinfection and inadequate cleaning of treatment tools, and in particular, ultrasonic cleaning for biopsy forceps wound with a spiral wire.

In the microorganism transmission report from Spach's, et al.,<sup>6)</sup> gastrointestinal endoscopy, a lot of infections occurred due to *Salmonella*, with 84 cases reported. Among those cases, fatalities due to septicemia were also reported. For almost all the cases, disinfectants with a relatively low disinfecting activity such as in, hexachlorophene, chlorhexidine, quaternary ammonium salts, etc., were used for disinfecting the endoscope against *Salmonella*.

##### 2) *Pseudomonas aeruginosa*

*P. aeruginosa* is bacteria that exist inside the intestines for 10% of healthy people, but it increases if there is just a little organic substance and water, and it is representative of a bacteria that takes to opportunistic infection in patients with increased susceptibility. In 1974, among 12 people whose esophagus was examined using a fiberscope, 3 patients with acute leukemia were infected<sup>3)</sup> with *P. aeruginosa*, and 2 fatalities were reportedly caused by septicemia according to the biopsy conducted. In other cases, there were infections due to *P. aeruginosa* after an endoscopic retrograde cholangiopancreatography (ERCP) procedure was performed, and it was reported that there was insufficient disinfection in the tap water from the water-supply bottle and the conditions inside the automatic cleaner, etc., were contaminated.

Table 1 Spaulding classification examples for endoscopic devices and materials

Disinfection level	Degree of injury or damage to the body	Infection risk	Instrument / Device
Critical (Sterilization)	Injure or damage mucous membrane (Falls into sterile range)	High	Biopsy forceps RCP imaging tube
Semi-critical (High level disinfection)	Contact with mucous membrane and skin wounds	Low	Endoscope
Non-critical (Low level disinfection or cleaning)	Contact with normal skin without wounds	Almost none	Cuff for taking blood pressure

Table 2 Microorganisms resistant to disinfectants

• Extremely High	: Prion ( Creutzfeldt-Jakob Disease)
• High	: Protozoan oocyst ( <i>Cryptosporidium</i> ) : Bacterial spores ( <i>Clostridium</i> , <i>Bacillus</i> )
• Slightly high	: Acid-fast bacteria ( <i>M.tuberculosis</i> , <i>M.chelonae</i> ) : Non-enveloped virus (HAV)
• Medium	: Among fungus, yeast ( <i>Cryptococcus spp.</i> ) : Vegetative bacteria ( <i>P. aeruginosa</i> , <i>Escherichia coli</i> , <i>H. pylori</i> )
• Low	: Enveloped virus (HBV, HCV, HIV)

### 3) *H.pylori*

*H.pylori* has been reported to cause acute gastric mucosal lesion (AGML) in patients after a gastroscopy procedure and it is known to be related to gastric carcinoma. *H.pylori* infection is caused by using inappropriate disinfectants and inadequate cleaning, such as wiping off an endoscope with alcohol after use or neglecting to brush down the endoscope suction channel, respectively.

In 1992<sup>9)</sup>, when investigating the blood of patient who become ill with acute gastritis after an endoscopy compared to the blood of 9 patients who received an examination with the same endoscope right before, *H. pylori* antibodies, that were not seen before the examination, were detected in 4 out of the 9 patients after the procedure. In addition, the infection was corroborated after finding the same gene sequence when the genetic type of *H. pylori* was analyzed for one patient.

### 4) *Escherichia coli* O157 (O157)

The virulence of O157 is extremely strong, infecting 100 times out of total 100 or so opportunities. In addition, a secondary infection is caused due to the long incubation period, from 3 to 8 days.

In 2003, an endoscope used previously on a patient with O157 was used in a colonoscopy procedure with another patient, the latter complained of diarrhea and abdominal pain. This patient fully recovered thereafter, but after checking the O157 genes from the former patient, it was revealed that the latter patient had the same gene sequence. There were problems with inappropriate cleaning methods, such as cleaning the endoscope inside a bucket instead of with running water, and problems with disinfection as well.

### 2. Virus

#### 1) Hepatitis B virus (HBV)

In 1983<sup>9)</sup>, a rupture in the esophageal varices occurred in a hepatitis B patient. In this case, despite the endoscope being immersed in disinfectant for 21 hours using a 2% glutaraldehyde (GA) solution, the scope was used the following day on a patient with gastrorrhagia, after which it was discovered that the patient became ill with acute hepatitis B 3 months later. In this instance, for the air supply and water supply channels, only the air supply was flushed with water and they were not disinfected. In addition, the type of endoscope used did not have an operation control section and connector part that could not be immersed in disinfectant.

## 2) Hepatitis C virus (HCV)

Since HCV has a small amount of virus in the blood compared to HBV, the infection goes unnoticed for a long period, according to an infection reported in 1997<sup>10)</sup>. After a patient with active hepatitis C, 2 patients received a colonoscopy 3 months later, and they contracted the infectious disease which was corroborated through genetic analysis. The problem areas were that the channels were not brushed, the scope was not sufficiently immersed in disinfectant and the biopsy forceps were not sterilized with ultrasonic cleaning and an autoclave, etc.

## 3. Fungus

With fungus, there was infection caused by *Trichosporon beigelii* reported<sup>11)</sup> in 1989. This bacteria was separated from the gastric juices in the patient, for 10 patients who received an endoscopy, and the source of infection was determined to be people with immunodeficiency.

## 4. Protozoa

With protozoa, in 1976 4 cases of esophagitis were reported<sup>12)</sup> using a scope that was contaminated with *Strongyloides stercoralis*.

## 5. Threat of microorganisms and risk of infection

The microorganisms that pose a threat for risk of infection include HIV, acid-fast bacteria, *Clostridium difficile* (*C. difficile*), *Cryptosporidium* and Creutzfeldt-Jakob Disease, etc.

1) HIV is a virus that is tremendously influenced by infection control, however there are no cases reported in which gastric transmission occurred related to the endoscope.

2) Acid-fast bacteria\* has a strong resistance against disinfectants for bacterial spores and endoscopic infection is mainly associated with *Mycobacterium tuberculosis* (*M. tuberculosis*) and *Mycobacterium chelonae* (*M. chelonae*). For bronchoscopy procedures, many infections are often attributed to *M. tuberculosis*, and there are also infections that are recorded due to *M. chelonae*<sup>13)</sup>. However, in gastroenterological endoscopy procedures, there are no infection reports of *M. tuberculosis*, and again, *M. chelonae* cleaner contamination cases have been seen but there are no reports of infection.

\*Difficulty with the stainability exists due to high level of lipids (waxy membrane constitutes 60% of the cell wall) in the cell walls with gram-positive bacillus, but once stained since it is not easy to decolor with acid and alcohol, it is referred to as acid-fast bacteria. In addition, among the acid-fast bacteria, the acid-fast bacteria that is not *M. tuberculosis* is known as nontuberculous mycobacterium.

3.) *C. difficile*\* is the causative bacteria for pseudomembranous colitis. Administering *C. difficile* resistant antibiotics to patients that carry this bacteria causes superinfection, and as a result *C. difficile* increases in the intestine and thus causes pseudomembranous colitis. In addition, this bacteria causes outbreaks in hospitals via healthcare personnel<sup>15)</sup>. However, there have not been any case reports of transmission with endoscopes.

\*This is an obligately anaerobic gram-positive bacillus that forms spores.

4) If HIV patients and patients who receive immunosuppressants are infected with *Cryptosporidium*\* oocysts, they become very susceptible to serious illness. It shows a high resistance to disinfectants, and GA disinfection is not effective. However, it perishes if left in 50°C conditions for 10 minutes, or if left for 3 hours in 22 to 25°C conditions, as it has weakness against drying. This means that it has poor substance permeability for disinfectants, etc., but it has a high water permeability<sup>16)</sup>. There are no reports of infection with endoscopes.

\**Cryptosporidium* is a microbial cyst (oocyst) that is wrapped in an egg-like shell and excreted together with the feces.

5) Creutzfeldt-Jakob Disease (CJD)\* is a spongiform encephalopathy that appears with aging between 50 and 60, with an onset ratio of 1 person out of approximately 1,000,000. If one is infected or becomes ill, it is fatal, and all disinfectants currently being used are ineffective. Since identifying and eliminating prions from endoscopes is difficult, there are those who advocate destroying and incinerating used endoscopes as the only means available. However, since there is no infectiveness in saliva, gingiva, intestinal tracts, feces or blood, in a draft report from the CDC, it claims there is no need to change current cleaning and disinfection methods. In addition, currently there are no reports of infection with endoscopes.

\*Note: Differs from CJD variant derived from BSE.

## 6. Safety of clean water

It is said that tap water (drinking water) is not sterilized, and because there is also risk of contamination of nontuberculous mycobacterium, sterile water and filtered water is preferred for cleaning and flushing endoscopes. However, it is actually difficult to raise the degree of cleanliness for all cleaning water across the board. And, if the residual chlorine concentration is maintained within the measurement range (more than 0.1 ppm), detection of bacteria (general bacteria, gluco-nonfermented gram-negative bacillus, etc.) will not be visible in a normal culture.



## Guidelines for cleaning and disinfecting endoscopes

Currently, there are no endoscope infection cases reported attributed to normal chlorinated water.

### IV. Contamination, cleaning, disinfection and sterilization

#### 1. Contamination

Contamination (dirt or stain) has some sort of combining power that functions between a solid surface and a foreign body, and the surface and foreign body bind with this strong power<sup>19)</sup>. The dirt or stain also includes organic substances, inorganic substances and microorganisms. Microorganism or microbial contamination on medical instruments and devices is the problem.

#### 2. Cleaning

Cleaning means eliminating or removing the dirt or stain from the solid body's surface. In cleaning, the surface tension is lowered while promoting solubilization, etc., due to the function of the chemical components which ultimately has a mechanical (physical) effect. Cleaning is an extremely effective adjuvant for microorganism removal, and before the disinfecting devices and materials, cleaning is conducted with detergent and warm water.

With cleaning, bio-burden (microbial count) is reduced, and resistive substances (organic substances and inorganic substances) are eliminated for disinfection and sterilization. As a result, cleaning should be done as soon as possible after use, because for things contaminated with feces, blood and mucus that are left out and dry up, the dirt or stain becomes more difficult to remove.

#### 3. Disinfection

Disinfection is a treatment method for killing or removing most or all of the microorganisms associated with the pathogens for diseases, excluding the bacterial spores from the targeted object. It is conducted using a chemical liquid agent and heat and humidity. The effects of disinfection will vary depending on various conditions. These include the types of disinfectants, the concentration, the temperature, the immersion time, the microbial type and the degree of contamination, as well as whether the disinfecting target has been cleaned or not, the configuration of the disinfecting target (things with spaces, tubular spaces) and whether there is a biofilm\* or not, etc. If the disinfectant is used inappropriately with something, not only will it be ineffective, but there is also an infection risk. Therefore, when using it, the appropriate disinfectant must be selected and it must be used with the proper concentration level for the most effective results.

\*Biofilm refers to the formation of membranous bacteria mass. It aggregates and interlocks with a fungus body that has glycoprotein (glycocalyx) on its surface, which is produced after immersing medical devices and materials with bacteria (*P. aeruginosa*, etc.) on them into a solution. Thus, it shows resistance against disinfectants.

#### 1) High level disinfectant

High level disinfectant kills all microorganisms excluding an array of bacterial spores and achieves sterilization after use over a long period. One example includes achieving chemical sterilization by using 2% GA over a 10 hour period. Note, there is no problem even if bacterial spores remain because the mucous membrane for the digestive tract, etc., is resistant to bacterial spores, but it would depend on the conditions and their susceptibility to infection for vegetative bacteria, acid-fast bacteria and viruses. There also is glutaraldehyde, phtharal and peracetic acid.

#### 2) Medium level disinfectant

Medium level disinfectant kills acid-fast bacteria, vegetative bacteria, and most viruses and fungus, and among these, there are some agents that also kill bacterial spores using a high concentration over a long period of time. There is also sodium hypochlorite, alcohol (isopropanol, ethanol) and povidone-iodine, etc.

#### 3) Low level disinfectant

Low level disinfectant is effective with almost all vegetative bacteria, fungus, and some viruses, but it is ineffective with acid-fast bacteria and bacterial spores. In addition, there are also many microorganisms that are resistant to the low level disinfectants. There are also quaternary ammonium salts, chlorhexidine and amphoteric surfactants, etc.

#### 4) Sterilization

There are some microorganisms that exist that cannot be killed regardless of the disinfection. Sterilization represents the level in which all microorganisms are killed. To be precise, everything is not exactly killed, rather the probability is infinitely close to zero.

For example, if there were 10 items among a given set of devices and materials, under certain conditions even if they are treated, when bacteria survives on one item, the probability of contamination is 1/10. The desired probability of bacterial contamination conditions with sterilization is less than 1/1,000,000. This means that there is 1 pair of contaminated biopsy forceps out of 1,000,000 pairs. 1 in 1,000,000 really means that it is close to zero probability, and sterilization is performed under conditions that allow treatment until achieving this level. For most sterilization levels, there is dry-heat sterilization, autoclave sterilization and ethylene oxide gas (EOG) sterilization, etc.

#### 5. Disinfectants used on endoscopes

##### 1) Glutaraldehyde<sup>20)</sup>

GA is a high level disinfectant that has been used and trusted as a disinfectant for many years.

It is effective with general bacteria, acid-fast bacteria, fungus, viruses, etc., and it is a bactericide that can maintain activity even with organic substances. There are problems with side effects due to exposure when disinfecting for a long period of time, but it does not corrode metal, rubber, plastic, etc., and it is therefore fitting for the disinfection of endoscopes which are delicate with heat. When disinfecting endoscopes, immerse in 2% GA disinfectant for 10 minutes, flush with water, and then perform additional drying with alcohol.

Drying with alcohol after disinfecting with glutaraldehyde is for controlling an increase in bacteria after it is dry. However, it is presumed that a bactericidal effect can be expected even with nontuberculous mycobacterium and *M. tuberculosis*, etc. in tap water. For this, an experimental disinfection with 2% GA was conducted immersing for periods of 10 minutes, 20 minutes and 45 minutes, after an endoscopic channel was contaminated with a quantity of  $10^6$  of an acid-fast bacteria *M. chelonae* and then given a standard wash by hand. The result of the experiment showed that 2 cases of 10 cases that were immersed for 10 minutes, 1 case out of 18 cases that were immersed for 20 minutes and 1 case out of 18 cases that were immersed for 45 minutes were not successfully disinfected. However, no bacteria were detected even after 10 minutes of disinfection for cases that were washed with 70% isopropanol (isopropanol alcohol) after a GA disinfection and then dried. In addition, even the GA resistant *M. abscessus*, which was not killed with the 2% GA disinfection for a period of 45 minutes, also relied on a 1 minute 80% ethanol disinfection to kill the bacteria<sup>22)</sup>.

Nevertheless, disinfection that relies only on alcohol is insufficient, and to produce this type of effect, one must begin by using this combination with a GA disinfection.

#### 2) Phtharal<sup>23)</sup>

Phtharal is commercially available in things with a 0.55% concentration level. High level disinfectants can be used in the presence of organic substances, and in 2001 it was approved by the Ministry of Health, Labour and Welfare as a high level disinfectant. 5 minutes should be sufficient for the disinfection time. In contrast to GA, it has a weak odor and is not very irritating for the skin and mucous membrane. It has excellent compatibility with materials and it has low adhesive properties for tissue and little blood coagulation on the surface of instruments and devices. It changes the color of organic substances, such as protein, to black, but this could indicate the cleaning process was inadequate.

#### 3) Peracetic acid<sup>24)</sup>

0.3% peracetic acid can be used for periods of 5 minutes for high level disinfection, and in 2001 it was approved by the Ministry of Health, Labour and Welfare as a high level sterilizer. The action mechanism kills bacteria through protein degeneration, the inactivation of metabolizing enzymes, and cell membrane destruction caused by strong oxidative potency, and cell wall destruction.

When peracetic acid is broken down, it becomes acetic acid, hydrogen peroxide, oxygen and water, so there are no harmful substances. The high disinfection effect of peracetic acid does not lose its efficacy even in organic substances, but it is highly corrosive with metals, and so to avoid corrosion, manufacturers adjusted the pH and launched not only a product that could be used with endoscopes but a specialized cleaner as well.

#### 4) Highly-acidic electrolyzed water (EOW)

The chlorine concentration for highly acidic electrolyzed water is 20 to 50 ppm with a pH of 2.7, and it can kill a lot of microorganisms in an extremely short period of time. It is not harmful to the environment and it also has the advantage of being reasonably priced<sup>25)</sup>. However, if more than 0.1% serum is added to the highly acidic electrolyzed water, the disinfection potency is offset<sup>26)</sup>. In addition, it only requires 1-2 minutes to kill acid-fast bacteria, but it also has a disadvantage because it is corrosive on endoscopes. Furthermore, when considering the disinfection effect and the stability, there is a need to use something with a stable chlorine concentration and pH, and endoscopic manufacturers are not recognizing the use of highly acidic electrolyzed water. As a result, the users of highly acidic electrolyzed water must manage it and shoulder the responsibility when using it.

### V. Endoscope structure and cleaning & disinfection

#### 1. Endoscope structure (Diagram 1 & 2)

The electronic endoscope is equipped with a miniature TV camera (CCD) on the tip of the scope, and it transmits the information as an electrical signal. The electrical signal is converted into an image signal by the video processor, and the image is shown on the TV monitor. All electronic endoscopes are made up of a connector, a universal cord, an operation control section and an insertion section. Endoscopes vary depending on the type and model, and some also have different parts depending on the manufacturer.

##### 1) Connector

The connector connects to the light source. There are air supply, water supply and suction channels, and it also has a light guide. The side of the connector connects to the scope cable, but before cleaning and immersing this section, fit the water-proof cap on it.

##### 2) Universal cord

The universal cord that continues to the connector is internally equipped with a light guide (comes from the glass fiber), air and water supply tubes, a suction tube and an image related cord.

## Guidelines for cleaning and disinfecting endoscopes

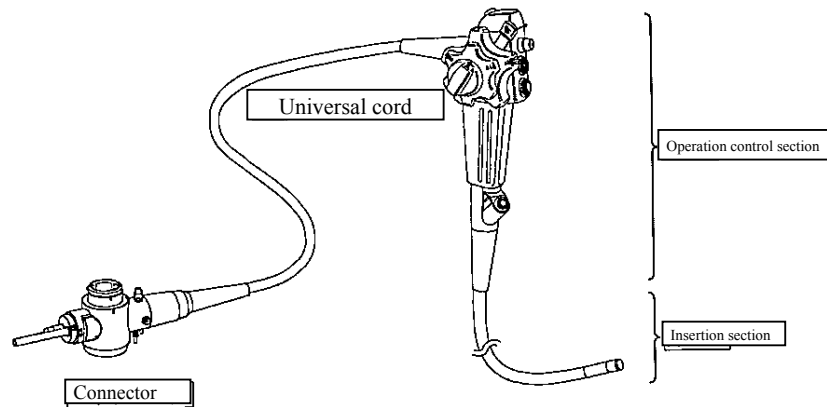


Diagram 1 Basic structure of gastroenterological electronic endoscope

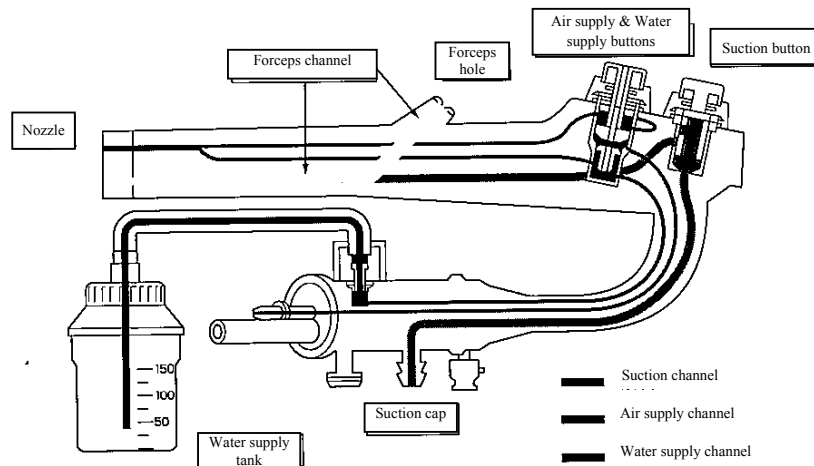


Diagram 2 Internal pipe line structure for gastroenterological electronic endoscope

During the endoscopy, the external surface may get contaminated from hand contact or splattering.

### 3) Operation control section

This section controls operations such as moving or securing the scope angle, and also using the buttons to perform suctioning, air supply and water supply operations. The operation control section can get contaminated during the endoscopy, and there are places where dirt and impurities are not easily visible such as the groove for the angle knob groove, or the support holes for the buttons. In addition, the insertion port for the biopsy channel is on the operation control section which is close to the insertion section, so it gets dirty easily and must be brushed thoroughly when cleaning.

### 4) Insertion section

The insertion section gets a high degree of contamination because it enters inside the patient's body. The tip of the insertion section ends at the opening of the suction and air supply and water supply channels. The section close to the tip is called the flexure. It is made from flexible material and if it is not handled with care, it may get scratched or damaged.

### 5) Common internal features

The suction, air supply and water supply channels stretch from the connector to the tip. When cleaning, be careful not to twist or bend the universal cord and insertion section at a sharp angle. If the biopsy channel is twisted, dirt and impurities can accumulate, and it may prevent you from cleaning thoroughly.

### 6) Special internal structure

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Side-view endoscopes and oblique-view endoscopes, etc., are equipped with a forceps raising wire channel and forceps raising mechanism, and this part requires a special measure for cleaning and disinfection.

### 2. Endoscope cleaning & disinfection

The reality is that endoscope cleaning and disinfection varies depending on various conditions of each facility. This is where we would like to present the cleaning and disinfection case examples in accordance with these guidelines.

#### 1) Bedside cleaning (Cleaning immediately after removal from the patient)

The healthcare personnel should wear protective gear such as a gown, gloves, eyewear, and/or a face mask in order to protect their body from hazardous substances from medicinal agents and infection when conducting cleaning and disinfection. Immediately clean the endoscope that is removed from the patient while it is still connected to the light source. This is because the external surfaces of the endoscope and the internal suction and air & water supply channels are exposed to fluids and other contaminants or pollutants. If the endoscope is not immediately cleaned, the contaminants adhere to the scope and dry up, and it becomes harder to clean.

(1) Wipe down the external surface of the endoscope with gauze or a cloth, in order to remove the mucous membrane, blood and filth that adhere to the external surface. Either moistened gauze or dry gauze is fine.

(2) Clean the inside of the suction channel. To clean, suction and flush 200 ml of enzyme detergent solution. The detergency or effectiveness of cleaning with water is not nearly as effective compared to enzyme detergent<sup>(27)(28)</sup>. When looking at the occult blood reaction for dirt, filth, etc., after suctioning and flushing with 200 ml of water, it is 100 positive, but after using an enzyme detergent solution, the positive ratio is 50% less<sup>(29)</sup>. When considering nozzle blockage, the enzyme detergent, which accelerates the breakdown of proteins, etc., is more appropriate than a neutral detergent. However, disinfectants (alcohol, chlorhexidine), rather than detergents, bind organic substances so they should not be used.

(3) An A/W channel cleaning adapter is included, and it is used to clean the air supply and water supply channels. To flush out gastric juices, intestinal fluids and blood (it is said that in the stomach, backflow occurs at the 15 cm marker) that backflow into said channels during the procedure, cleaning with this adapter is effective in preventing nozzle blockage and also for protection against infection.

(4) The tube that connects to the water-supply bottle and the scope cable that connects to the light source are the parts that connect to the scope connector. Normally the degree of contamination is low and the possibility of transmitting infection to the patient from there is also low, so alcohol soaked gauze and a low level disinfectant, etc., can be used to disinfect by either wiping or immersing.

In addition, there is filth and dirt that adheres to the end of the suction tube that connects to the endoscope suction cap, so to finish, use the same gauze to wrap and cover that part then disinfect so as to avoid splattering the surroundings.

#### 2) Leakage test

Remove the light source from the endoscope and attach the water-proof cap. Run water into a basin or sink. Attach the connecting port for the leakage tester to the ventilation clasp on the water-proof cap. While the leakage tester is attached, immerse the endoscope into the water, and check that there are no bubbles coming continuously from the endoscope. Due to the number of procedures, performing the leakage test every time is difficult, but performing it after every case certainly helps prevent major repair work. There are leakage test accessories for attaching to automatic cleaners, for devices that use a light source and for specialized devices or tools.

#### 3) External (outer surface) cleaning on endoscope

Remove the dirt and filth from the external surface of the endoscope with a sponge or gauze, etc., using detergent (neutral or enzyme detergent, etc.) while rinsing with warm water. In particular, be sure to carefully clean the operation control section and the insertion section on the endoscope. For the lens surface on the end, clean it with a soft brush.

For endoscopes equipped with a forceps raising mechanism, since it is difficult to remove dirt or filth using a channel cleaning brush or with a soft brush because of the complex structure of the device, use an automatic toothbrush device with pulsating water (water spurts out intermittently), which has a good cleaning effect. In addition, flush or feed water through the raising forceps pipe (3 - 5 ml). Here, check to make sure the discharged fluid is clean and clear.

#### 4) Cleaning accessories

Remove the air supply and water supply buttons, the suction button and the forceps plug, and clean each. It is difficult to remove dirt and filth from the forceps plug in particular, so be sure to open the flap and clean with a brush, and then wash and rinse thoroughly by hand.

#### 5) Brushing the suction and forceps channels

Brushing the forceps channel can be performed either under running water or in an enzyme detergent solution. Use a channel cleaning brush, and each time the brush pokes out from the end, scrub and wash with tap water. Even if you disinfect thoroughly with the appropriate disinfectant, there do exist infection cases due to neglecting the channel brushing stage. As a result, brushing is an important point to protect against infection. Use the channel cleaning brush for all 3 places on the suction and forceps channels.

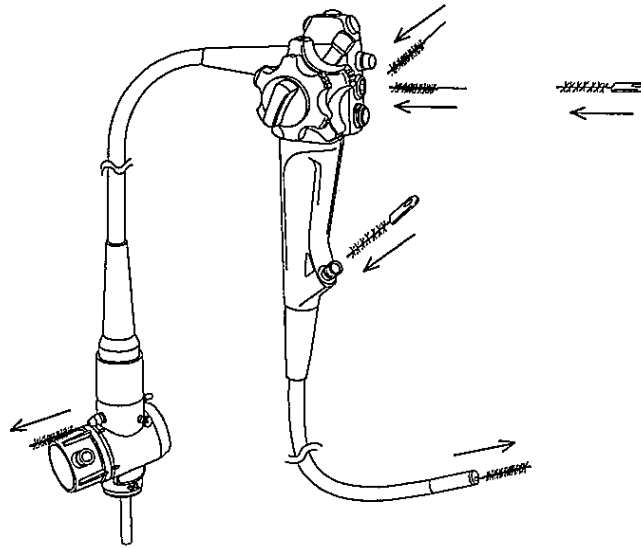


Diagram 3 Brushing the suction and forceps channels

The 3 places mentioned specifically refer to the segments: from the suction button position to the suction cap, from the same suction button position to the forceps outlet, and from the forceps insertion port to the branching section for forceps channel (Diagram 3).

As far as amount of brushing required, it varies depending on the type of procedure, such as observation only, a biopsy, or treatment, as the degree of contamination also varies significantly for each type. In addition, there is a limitation with the effectiveness in brushing, it has a lower eliminating effect for blood clotting in particular\*. In order to get more assured results, it is necessary to not only perform brushing but also flush/suction and immerse with an enzyme detergent. As a result, for cases where the dirt and filth is extremely hard to remove, perform brushing until it is removed, that is, stop brushing after checking that the dirt or filth is removed. Use a brush that is appropriate for the forceps and do not use one that is deteriorating or worn.

\*Results from the occult blood reaction test showed 78% positive after brushing twice under running water<sup>29)</sup>.

#### 6) Immersion in enzyme detergent solution

Cleaning endoscopes by immersing them in the economically priced neutral detergent may be sufficient according to some. However, if one considers that checking inside the channel cannot be done and that there may be obstructions in the air and water supply nozzle or that there may exist a small amount of dirt or filth that has adhered internally, then one arrives at the conclusion that enzyme detergent solution should be used. When using the enzyme detergent solution, first use a channel cleaning device (a device for cleaning all pipes, etc.) and after immersing it in an enzyme detergent solution, thoroughly flush out all bubbles inside the channels

and continue until all channels have been filled with the enzyme detergent solution.

Follow the specified concentration and specified time period (2 – 5 minutes) when immersing with the enzyme detergent solution. If heated to a temperature level between 35 – 40°C, protein binding is not usually seen, and one can expect a better cleaning effect if the temperature is higher than room temperature. In an endoscope the average amount of bacteria that adheres inside the channels is  $10^5$  cfu/ml<sup>30)</sup> and by cleaning with this immersion method, this amount can be reduced to less than  $10^2$  cfu/ml.

#### 7) Rinsing

Put the external surface of the endoscope under running water, and attach the channel cleaning device for the suction and biopsy forceps channels and rinse thoroughly.

#### 8) Disinfection

After use, if the endoscope is disinfected without cleaning first, the microorganisms will bind to the endoscope. As a result, this will not only obstruct cleaning but it will also in fact protect the pathogenic microorganisms. This invites the possibility and cause for infection and should never be done. For high level disinfectants for endoscopes, the Ministry of Health, Labour and Welfare has currently approved GA, Phtharal and peracetic acid. As a consequence, the effective concentration and time limits should be followed when using the various pharmaceutical and medicinal agents. However, medium level disinfectant alcohols and low level disinfectants such as benzalkonium chloride and chlorhexidine gluconate cannot be expected to be effective and should not be used.

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In the GA disinfection cases, detergent was thoroughly used to clean and remove impurities, then in a basin for GA immersion, the external surface of the endoscope and all the endoscope channels were immersed for 10 minutes using more than 2% of GA.

### 9) Rinsing the disinfectant

Put the external surface of the endoscope under running water, and attach the channel cleaning device for the suction and biopsy forceps channels and rinse and flush more than 200 ml of water\*.

\*There are reported cases of proctitis and mucosal damage when GA was leftover in a colonoscopy due to a lack of thorough rinsing.

### 10) Drying

Run more than 10 ml of 70% of isopropyl alcohol and 70% ethanol for each channel, and dry by aerating or suctioning.

This procedure was already mentioned in the Glutaraldehyde section, but by conducting additional drying with alcohol after disinfecting in 2% GA for 10 minutes, one can expect an effect even for acid-fast bacteria such as *M. tuberculosis*<sup>21)22)</sup>. As a consequence, even if the endoscope is to be used right away, it is necessary to perform this procedure\*.

\*Alcohol may remain after this treatment procedure, so be sure to aerate or suction the inside of the channels with water.

In addition, always use GA in conjunction with alcohol disinfection. Do not ever perform GA disinfection alone.

### 11) Storage

If there is moisture remaining inside the channels of the endoscope, bacteria may grow and increase while being stored, so dry the endoscope thoroughly to prevent bacterial growth. Therefore, hang the endoscope on a hanger when storing without attaching the air supply & water supply buttons, the suction button and the forceps plug.

### 12) Cleaning with the cleaners/purifiers

Cleaning with cleaners and purifiers should be only be performed after conducting endoscope suction cleaning, washing the external surfaces of the endoscope, and brushing the suction and biopsy channels. If cleaning is not performed up to this level, you will not be able to completely clean and disinfect the endoscope thereafter. Cleaning with the cleaner or purifier simply entails turning on and applying the cleaner device to the endoscope, and then store it. As a precaution, since the user of the cleaner device handles contaminated endoscopes as well as treated and cleaned endoscopes, be sure to clearly separate the contaminated endoscopes and those that

are cleaned.

## VI. Cleaning, disinfecting and sterilizing endoscope accessories

With the advancement in endoscopy procedures and medical treatment, the endoscope resources have also diversified. The inadequate reprocessing of biopsy forceps after use has caused infection cases with *Salmonella* and *H. pylori*.

### 1. Treatment tools

#### 1) Biopsy forceps

Biopsy forceps are a tool that carries the risk of damaging aseptic or germ-free tissue, and pieces of tissue, blood and mucus always adhere to them. Since this device has a wire for closing and opening the forceps and since there is a spiral wire that covers the forceps, the blood and mucus that infiltrates in between the wiring cannot be removed with general cleaning using a brush. Currently the most effective cleaning method is ultrasonic cleaning.

After using the biopsy forceps, immerse them in enzyme detergent, and clean them for 30 minutes with the ultrasonic cleaning device. Thereafter, rinse with water, pat dry, apply a lubricant, lightly rub it off, and sterilize. If sterilizing the biopsy forceps in an autoclave (i.e., 134°C for 3 minutes<sup>32)</sup>, etc.), its safety cannot be guaranteed. This method is also effective with bacterial spores and viruses. When using other methods, problems arise. For example, it is normally difficult to completely dry biopsy forceps and if dirt or filth and water remain, the forceps cannot be adequately sterilized using the ethylene oxide gas (EOG) sterilization method.

#### 2) Snare and clipping devices

These devices have an interwoven wire or a spiral wire, which is made with a Teflon sheath that encapsulates it. After use, remove the wire from the sheath, place both into an ultrasonic cleaner with enzyme detergent and clean for 30 minutes. During this time, the cleaning solution completely fills up inside the sheath. Thereafter, rinse with water, pat dry, apply a lubricant, lightly rub it off, and sterilize it in an autoclave.

#### 3) Grasping forceps and basket forceps

Grasping forceps and basket forceps, etc., are made in such a way that removing the wire and sheath for cleaning cannot be done. Instead, a solution feed plug is included for cleaning purposes. Fill the sheath with a cleaning solution through the solution feed plug, and clean for 30 minutes with the ultrasonic cleaning device.

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After cleaning, rinse the solution feed plug thoroughly with water, and then flush the water out. Thereafter, run a lubricant through it, then conduct an operation check and sterilize it in an autoclave. However, do not use a lubricant for operation control sections that do not have an imaging tube.

### 4) Disposable products

Treatment tools such as biopsy forceps and snares, etc., are made up of an inner wire and outer sheath. If they harm mucous membranes, they can become contaminated by blood and mucus, etc., for which cleaning and sterilizing is a difficult task. As a result, re-usable products as well as disposable products are also being developed. Disposable products are not necessarily considered for use again, so they should not be reused. Reusing disposable products makes using what would be safe products in a hazardous or at risk state. Specifically, since there are many treatment tools which have complex structures, if they are not sufficiently dried after cleaning, the risk of infection is high.

### 2. Water-supply bottle

If a sterilized bottle is filled with tap water (drinking water), and the same bottle is used left for a week straight, when it is attached to a light source or the connector section, *P. aeruginosa* is introduced. As a result, bacteria growth incurs and 1/3 becomes culture-positive<sup>33)</sup>. However, normally the ratio of culture-positive bacteria inside a standard bottle is low. Even if a bottle is sterilized once a week, when the bottle is dried out every day, there is almost no bacteria (general bacteria and gluco-nonfermented, gram-negative bacillus, etc.) detected. Nevertheless, for patients with increased susceptibility for whom there is a risk of causing an infection, sterile water is recommended for use.

### 3. Automatic cleaner/purifier

Even though this may be repetitive, there are cases reported where the wash or cleaning basin and the water supply piping for the automatic cleaners/purifiers were contaminated with *P. aeruginosa* and nontuberculous mycobacterium (*M. chelonae*, etc.). In particular, if the GA concentration is lowered, there is risk of being contaminated with nontuberculous mycobacterium<sup>14)</sup>, and as a result, the cleaners and purifiers themselves must be disinfected regularly.

## VII. Examination conditions

Generally speaking, even though the examination table, the light source, and the biopsy tissue treatment table is easily contaminated, the floor, walls and curtains generally do not get contaminated. Yet, sinks and other basins that normally get contaminated with gram-negative bacillus, such as *P. aeruginosa* and *Serratia spp.*, are usually not the source of infection.

### 1. When uncontaminated

The conditions for the examination or procedure include things that do not engage in skin contact and therefore there is almost no risk of infection for the patient. As a result, it is classified as non-critical, and when uncontaminated, cleaning is more important than disinfection.

Many of the organisms that exist on the floor are nonpathogenic bacteria such as coagulase-negative staphylococcal, etc. In addition, conditions, such as the floor influencing infection, that relate to percentage of infection is extremely small<sup>34)</sup>. There is no difference in the percentage of infection when the cleaning the floor with detergent or when cleaning with disinfectant. In a cleaning survey concerning the floor, there was an 80% reduction in the amount of bacteria after cleaning, and a 99% reduction after cleaning with disinfectant. It was observed that there was a larger reduction of bacteria when using disinfectant. However, it was reported that after 2 hours elapsed since being disinfected, almost all of the bacteria that existed before disinfection returned<sup>35)</sup>.

### 2. When contaminated

It is believed that there is almost no incident of infection from the examination conditions, but it is necessary to consider the possibility of MRSA and *P. aeruginosa* infecting patients with increased susceptibility. Furthermore, HBV has the ability to infect and can last up to a week even under dry conditions. Accordingly, if the surface conditions are slightly contaminated, a blanket bath is given with 0.1% sodium hypochlorite, and if the blood contamination is visible, the disinfection effect will lower due to microorganisms, so a blanket bath is given with 0.5% sodium hypochlorite<sup>36)</sup>.

### 3. When there is no disinfectant effect or there is a reverse effect<sup>37)</sup>

Normally the procedure room for the endoscopy is cleaned, and maintaining a clean environment is fundamental for preventing infection. However, there are cases where it is meaningless to change to disinfection or where it may be harmful.

1) For the method in which disinfectant is put into the suction bottle ahead of time, not only will it have no effect in reducing the microorganisms and lowering the concentration for suction, but the economic savings or necessity is also extremely low.

2) There is no need to use a high level disinfectant such as GA for disinfecting the discharge, that comes from treating or reprocessing the endoscope and suction bottle used on patients with HBV and HCV. Using a low level disinfectant or a detergent to remove the contamination is more than enough.

3) There are problems with side effects due to exposure to GA so never use GA to disinfect the floor that has been contaminated with HBV or HCV infected blood.

## VII. Endoscopy safety measures for healthcare personnel

During an endoscopy, not being careful about the risk of infection for the healthcare personnel themselves, such as the physician performing the endoscopy, endoscopy technician or the nurse practitioner, describes the actual situation. However, there does exist an infection risk, so its importance should be emphasized in the same way as for the potential endoscopic infection toward the patient.

### 1. Infection risk

There are a lot of HCV infection case reports<sup>38)</sup> for the healthcare personnel related to endoscopy procedures, and among them, there is even a case of a fatality caused by fulminant hepatitis. In addition, for physicians who perform endoscopies without gloves, there is a high *H. pylori* antibody prevalence, and touching patient's mucus with bare hands can lead to infection transmitted orally<sup>39)</sup>. Also during a biopsy procedure, there is high exposure for assistants through the surgeon or technician<sup>40)</sup>. The estimated fluid exposure to the eye due to splattering for physicians who perform endoscopies is 4.1%<sup>41)</sup>. Furthermore, there is also a case report<sup>37)</sup> for medical practice in the U.S., where a healthcare employee contracted a gastric infection due to conjunctival exposure.

### 2. Prevention measures for infection routes<sup>42)</sup>

#### 1) Contact infection

Prevent the transmission of infectious disease through patient contact or contact with medical instruments and devices and with surface conditions. Wash your hands, and wear gloves and a gown (apron).

#### 2) Droplet infection

Prevent the transmission of infectious droplet nucleus (bigger than 5 $\mu$ ) through tracheal aspiration, coughing, sneezing, and conversation. Wash your hands and wear a mask.

#### 3) Air-borne infection

Prevent the transmission of infectious droplet nucleus (Smaller than 5 $\mu$ ) that are suspended in the air for a long period of time. Ventilate 6-12 times in one hour (use a HEPA filter) using a special ventilation measure (negative pressurized room, etc.), and use a N95 fine particle mask.

### 3. Preventive measures against infection in endoscopy rooms

It is known that there is risk of infection during an endoscopy procedure, but regardless if staff wears gloves and a gown during the endoscopy, there are almost no incidents with those people who wear protective wear for the eyes and face. However, it is impossible to avoid airborne droplets that come at you.

To prevent infection, it is essential to use gloves, gowns (apron), goggles, (face shield) and masks, etc. After use, prohibit the recapping of needles, etc., and it is imperative to consider disposing needles into a specific throw-away box.

There are reports that incidents of accidental needlesticks were reduced by 25% from using a disposal box for used needles<sup>43)</sup>. In addition, be careful not to touch phones and medical charts with contaminated gloves. Replace towels, etc., used on patients for biopsy procedures and treatment.

### 4. Handwashing

Handwashing is fundamental for infection prevention, and wash according to the guide<sup>44)45)</sup> for handwashing and hands and fingers disinfection. Use an alcohol-based antiseptic hand rub if your hands are not visibly dirty. Wash with soap and running water if the dirt or filth is visible or for protein contamination. This is the procedure for handwashing with soap and running water: first, wet your hands, then put soap on them, and lather and rub them all around for 15 seconds, then rinse with water and completely dry them with a paper towel. This procedure requires 30 – 60 seconds, but many complete the process in just 10 seconds and do not wash sufficiently. Furthermore, the average for the ratio of people who perform handwashing is low at 40%<sup>46)</sup>.

On the other hand, as far as an alcohol-based antiseptic hand rub, while it is not fitting for dirty hands, it can kill or sterilize transient bacteria adhered to your hands. If you carry it with you, you can use it anywhere. Since it has a protective agent, it is less irritating on your skin than soap, and in addition, it also has advantages such as being able to reduce or provide care for rough hands.

### 5. Handling infections

Since the presence of infection cannot be determined immediately, make an infection prevention manual at each facility, and make preparations to be able to respond quickly to any incidents.

#### Incident response

1) For skin infection, after rinsing thoroughly under running water, wash and flush with soapy water.

2) For eye infection, wash and flush thoroughly with running water.

3) For an oral cavity infection, gargle thoroughly with water. (If a povidone-iodine solution is used, it has a disinfection effect)

4) For an accidental needlestick, immediately wash and flush thoroughly with running water, then wash and flush with soapy water, and quickly disinfect with 0.1% sodium hypochlorite. Sodium hypochlorite reacts to proteins, because it converts to common salt, it is the lowest residual disinfectant

<sup>47)</sup>. For incident reports, the type of incident (needlestick, airborne droplet contamination, contact infection, etc.), the time and date of the incident, and the factors or conditions surrounding the incident should be reported, and a breakdown of the cause and preventive measures to avoid reoccurrence would be helpful.



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### 6. GA toxicity

GA exposure causes dermatitis, rhinitis and conjunctivitis, etc. In addition, if continuously exposed to high GA concentration levels under extremely poor ventilation conditions, separate exposure to even the slightest amount of chemical substances may result in an outbreak of stomatitis or lead to complaints of throat and pulmonary pain, that is chemical sensitivity. For countermeasures against GA exposure, one can reduce the concentration level in the air as much as possible, but in Japan there is no legal regulation. In the Occupational Safety and Health Administration (OSHA) in the U.S., there is a regulation for health management stating that the concentration level shall not exceed 0.2 ppm. Furthermore, the American Conference of Governmental Industrial Hygienists (ACGIH) recommends that GA concentration levels be under 0.5 ppm.

In order to protect yourself from GA exposure, set up a special GA exhaust system on the portion of the floor exposed, or set up a local exhaust ventilation system inside a box to intensify the emissions and process them. When performing cleaning and disinfection, wear a face shield (goggles), special mask, waterproof gown (apron) and gloves (elbow-length) in order to minimize vapor inhalation and skin contact. Apply protective skin cream for your arms.

In order to avoid GA exposure, use an automatic endoscopic cleaner when possible, and set up a special exhaust system. However, for facilities that do not have these types of resources, ventilate well by opening windows. In addition, make sure to always carry out the exposure countermeasures for not only GA but other disinfectants.

### 7. Health management

Healthcare personnel compared to the general population have a high HBV antibody prevalence rate<sup>48)</sup>. The risk of HBV infection varies depending on the viral load included in the blood and mucus and excretions, etc. However, the infection rate for needlesticks due to HBe antigen-positive blood is 30% higher, and for people who do not have HBV antibodies, they can receive a vaccine inoculation.

### XI. Quality Control for endoscope cleaning & disinfection

In order to prevent infection from endoscopes, cleaning and disinfecting are performed, but there are some concerns about whether the scope is completely safe after cleaning and disinfection. For this, the Japan Gastroenterological Endoscopy Society recommends a Quality Assurance<sup>49)</sup> program for the guidelines in place.

1) For each facility, perform a general bacteria culture test for the surfaces and forceps channels on endoscope devices and treatment tools extracted randomly.

2) The extracted scopes that apply shall include all types used in that facility such as for the superior parts, inferior parts and duodenum.

(1) Run 20 – 30 ml of sterile physiological saline through the scope channels, and perform a direct culture.

(2) Perform a culture test by swiping on the scope's surface.

(3) Perform a culture test with the most appropriate method on the peripheral devices (including items in storage).

This is an endoscopic cleaning and disinfection target for the guidelines, and in theory if the guidelines are followed, then there should be no bacteria detected on a standard scope. If cleaning and disinfection is performed at a standard level that is below the guidelines, then the probability that bacteria will be detected is high. If the results from the survey test show that bacteria was detected, regardless of the bacterial strain that is detected, it is required to improve the cleaning and disinfection methods, excluding cases where a mistake is made when the bacterial contamination is falsely reported during the search.

However, even if bacteria detected from the peripheral devices, it is not a problem if the bacterial strain is coagulase-negative staphylococcal, or *Bacillus spp.* gram-negative bacillus, as they already exists in a normal environment. Note, if the device or tool is visibly dirty (blood, mucus, feces, etc.), the dirt or filth must be removed and cleaned. Use detergent to remove that. In this situation, a surface-active agent (cleaning agent) with a disinfection effect is more effective. With peripheral devices, it is necessary to clean to maintain a hygienic conditions and sanitation.

### X. Conclusion

There are facilities that do not clean and disinfect thoroughly. However, infection cases from gastroenterological endoscopy procedures are rarely reported, and with methods that are not based in the general principles of infection control, there are infection risks that exist. Certainly there are financial burdens that correspond to following to the guidelines, but if an accidental infection were to occur, the financial and social losses would be immeasurable.

In addition, in order to reduce the financial burden, an assessment of the medical service fees is needed in order to apply the National Health Insurance point system to cleaning and disinfection. Furthermore, the appropriate regulations from the Ministry of Health, Labour and Welfare are required in order to disseminate the guidelines.

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Endoscope cleaning and disinfection is a task that requires time and effort, but it is an extremely important duty for protecting patients from the risks of infection. If the cleaning and disinfection guidelines cannot be strictly followed, the healthcare personnel associated with endoscopy should be well aware that endoscopy procedures and treatment will not be able to maintain itself. In conclusion, we would like you to utilize these guidelines to create manuals at each facility and set up safe endoscopy procedures accordingly.

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Guidelines for cleaning and disinfecting endoscopes

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