

Guidelines for reprocessing non lumened heat sensitive ENT endoscopes

M. Cavaliere, M. Iemma

Struttura Complessa di Otorinolaringoiatria, Azienda Ospedaliera Universitaria "San Giovanni di Dio e Ruggi d'Aragona", Salerno

SUMMARY

Endoscopes have become an indispensable instrument in the daily activity of the ENT department, but their use has introduced potential health risks such as the transmission of infection.

Over the years scientific knowledge has been consolidated regarding the most appropriate ways for the correct disinfection and numerous guidelines have been issued for both digestive and respiratory endoscopes, while to date specific references to ENT endoscopes do not exist.

The diagnostic ENT endoscope does not generally have an operative channel, it is shorter, thinner and has a much more frequent usage, also in the out-patient setting. As a consequence the guidelines for digestive or respiratory endoscopes are not always functional for the ENT department in that they do not take into account the dynamics or the intensity of the work performed therein.

This paper proposes:

- To standardize the correct way to carry out the disinfection procedure of heat-sensitive non-lumened ENT endoscopes in order to reduce to a minimum the possibility of errors or oversights.
- To guarantee the disinfection within a limited time frame, appropriate for an ENT out-patients department.

In the initial phase the critical areas encountered in ENT endoscopy were determined. This was followed by a research of the literature in order to identify existing guidelines for the reprocessing of endoscopes (mainly digestive and respiratory) with a view to establishing a common disinfection procedure of non-lumened ENT endoscopes. Finally, the new methods of disinfection, developed specifically for the reprocessing of ENT endoscopes were examined and discussed.

KEY WORDS : Heat-sensitive ENT endoscopes • Cleaning • Disinfection

Introduction

Endoscopes have by now become an irreplaceable instrument in the daily activity of an Otorhinolaryngologist, guaranteeing incomparable vision and viewing ability.

Their introduction into clinical practice has therefore undoubtedly improved the diagnosis and treatment of numerous pathologies but has also brought about new health risks such as the transmission of infections.

A study by the American Society for Gastrointestinal Endoscopy¹ has calculated the incidence of infection to be 1 per every 1,800,000 endoscopic procedures performed (0.000056%).

Although this level of frequency may seem low, given the high number of endoscopic procedures performed on a daily basis throughout the world, endoscopy-related infections remain those most often associated with the medical device.

Many studies²⁻⁴ agree in affirming that in nearly all of the infections transmitted to the patient after an endoscopic exam, a defect in the cleaning and disinfection procedure was shown to exist. This can occur in particular during:

- the pre-washing step (12%);
- the washing/disinfection step (exposure time, inappropriate disinfectant) (73%);
- drying and storage (12%).

Flexible endoscopes are heat-sensitive and therefore cannot be sterilised in an Autoclave but must be disinfected^f

In recent years, scientific knowledge has become consolidated on the most appropriate and correct methods of disinfection resulting in the creation of numerous Guidelines in both Digestive and Respiratory Endoscopy, whereas in Otorhinolaryngology, to date, no specific references yet exist.

ENT diagnostic endoscopes, although conceptually similar to gastroscopes or bronchoscopes, are different owing to the absence of the operating channel, their smaller size and delicateness and moreover their more frequent use, including in outpatient situations. As a result, the Guidelines used in Digestive and Respiratory Endoscopy are not always functional in the ENT Department since they do not anticipate the dynamism and intensity of the work carried out there.

Objectives

This document, which specifically concerns heat-sensitive non-channelled ENT Endoscopes, proposes to:

1. standardise the correct method of execution with regard to disinfection procedures for heat-sensitive non-channelled ENT Endoscopes
2. Prevent the transmission of infections;
3. Increase operator safety;
4. Guarantee disinfection under tight deadlines in timeframes suitable for an ENT outpatient facility;
5. Critically evaluate the most significant problems anticipated in the application of these directions into practice.

Methods

In the initial phase, we identified the main areas of criticality within ENT endoscopy departments.

Next, we researched the literature to find all the Guidelines on reprocessing endoscopes published at the international level (for Digestive and Respiratory Endoscopy) with a view to discovering a common disinfection procedure for heat-sensitive non-channelled ENT endoscopes.

We also identified and discussed new disinfection methods designed specifically for the reprocessing of ENT endoscopes.

Risk of infection in endoscopy

The risk of infection is inherent in patient care practices. The interaction between a pathogenic agent (bacterium, virus, fungus, parasite or prion) and a susceptible host can give rise to three different scenarios⁶:

- *Contamination*: the presence of a micro-organism not capable of reproducing, in the absence of clinical manifestations.
- *Colonization*: the presence of micro-organisms capable of successfully reproducing, in the absence of clinical manifestations.

- *Infection*: the growth and proliferation of micro-organisms, in the presence of an immunological response on the part of the host even if not necessarily entailing clinical manifestations.

The sources of infection are therefore represented by infected or colonized patients.

The environment is also a major source of infection⁷, in particular with respect to the quality of water used to rinse the endoscopes. Where possible, rinsing in sterile water is recommended. Otherwise, rinsing in high-quality drinking water is also acceptable. When using drinking water for rinsing, the user should be aware of the higher risk of recontamination of instruments with microorganisms that may be present in the water supply. Utilization of a bacteria-retentive filtering system (0.2µ) can help to eliminate or considerably reduce the quantity of bacteria transmitted by drinking water.

An observational study conducted at 26 hospitals in the United States revealed that the majority of endoscopes and bronchoscopes were being improperly disinfected⁸ owing to: use of an inappropriate disinfectant solution, failure to routinely check the disinfectant's concentration, failure to clean or wash all the parts of the endoscope, failure to measure manual disinfection times and failure to completely immerse the endoscope in the disinfectant solution.

The *degree of risk* is classified as:

- Low for patient care that involves only direct contact with healthy skin;
- Intermediate when there is contact with the mucous membranes or superficially damaged skin;
- High for patient care that involves penetration into tissue or sterile cavities or entry into the vascular system.

The degree of risk determines the reprocessing level of the instrument used: endoscopes (entering into contact with mucous membranes or damaged skin), according to Spaulding's classification, are considered *semi-critical medical devices for which the risk of infection is intermediate* and for which *high-level disinfection* is required⁹⁻¹¹.

High-level disinfection presumes the inactivation of all vegetative forms of bacteria, mycobacteria, fungi and viruses, but not necessarily of all bacteria spores.

The goal is to bring the endoscope up to a level of safety whereby it does not represent a means of transmission of pathogenic micro organisms or other potentially dangerous chemical substances for both the doctor and the patient.

High-Level Disinfection of Endoscopes ^{10 12-21}

The goal of disinfection is to prevent the transmission of infections between users and health professionals. We have categorized disinfection systems into two types:

- *Traditional*, that is systems acquired principally from digestive and respiratory endoscopy:
 - *Immersion*: the operator manually performs all the steps involved in disinfection;
 - *Automatic*: systems in which disinfection and if applicable pre-washing and drying are handled automatically without manual intervention.
- *Emerging*, methods designed specifically for the organizational needs of the ENT Department:
 - *Complete reprocessing using wipes*;
 - *Immersion systems electronically controlled by a microprocessor*: part of the process is consigned to the operator (in general the pre-washing, rinsing and drying) and part occurs automatically (disinfection with time calculations, disposal of the disinfectant).

Contact between the disinfectant and skin is practically non-existent: the device is positioned in the empty unit and is removed only when the disinfectant has been emptied out;

- *Sheaths*: constitute a protective barrier of the endoscope from contaminations and not a system of disinfection.

The effectiveness of disinfection is dependent upon numerous variables such as:

- The basic level of contamination;
- The cleaning previously done: the greater the microbial load, the more difficult it is to obtain a good result;
- The disinfectant solution used, its concentration and contact time;
- The physical characteristics of the object to be disinfected;
- The temperature and pH in which the process occurs.

The steps to reprocess endoscopes common to all traditional disinfection systems are laid out in Table I.

Before going into the details of each individual step, we must first emphasize the following two points:

1. *Reprocess the endoscope immediately after use*: if it is left dry for a long period, residues can dry out causing encrustations and damage to the instrument;
2. *The entire endoscope must be cleaned and disinfected*: to be avoided are the wall viewfinders in which the optical unit would remain untouched by the disinfectant resulting in a continuation of contamination.

After analysing the reference literature, the working group suggests the following recommendations divided according to the type of disinfection system.

Table I. Endoscope disinfection treatment steps.

Steps	Goals
1. Disconnecting and inspecting the endoscope.	1. Check the integrity of the seal
2. Manual cleaning	2. Eliminate dirt with manual action and also using a cleaning solution
3. Manual rinse	3. Eliminate dirt and cleanser
4. Disinfection (automatic, by immersion or by immersion electronically controlled by a microprocessor)	4. Eliminate all micro organisms
5. Final rinse (automatic or manual)	5. Eliminate disinfectant residues
6. Drying (automatic or manual)	6. Eliminate residual water to prevent a damp environment that encourages the development of micro organisms
7. Storage	7. Keep the endoscope at a low microbial load
8. Ability to track the procedure	8. Document and record disinfection treatment steps

Traditional Systems

1. *Manual disinfection system by immersion*

Step 1. Disconnecting and inspecting the endoscope

- At the end of the endoscopic exam, disconnect the instrument from the light source after turning off the light.
- Clean the endoscope by holding gauze in your hands and wiping the instrument up and down in order to eliminate any adhering organic residues.
- If disinfection occurs in a separate, specific location (which is highly preferable), the transport procedure must prevent contamination of the environment as well as that of health professionals. Containers used for transport must therefore be equipped with a cover, made of the appropriate material and be of the right size so as to facilitate cleaning and disinfection of the instrument in addition to protecting it during transport.
- After reaching the washing room, a leak test is to be conducted before submitting the instrument to disinfection procedures. Using an active and connected tester, tilting motions of the instrument are to be carried out so as to better highlight any areas of damage. If any losses of seal are observed, immediately contact the firm for repairs; a damaged area detected within a short timeframe limits the cost of repair which rapidly increases if the instrument continues instead to be used.

Step 2. Cleaning with a cleaning solution

- The result of a good cleansing action leads to a reduction in microbial contamination by as much as 90%, a prerequisite for the successful disinfection of the instrument.
- An enzymatic cleaning solution is necessary which must be changed after every use since it does not have any biocidal activity and thus allows germs to survive in it. The AOOI study demonstrated that at least 42 % of operators reuse the same cleaning solution. Even after verifying those that use a cleanser with disinfectant properties, a consistent number are still making a technical error.
- Completely immerse the instrument in the cleaning solution in strict compliance with the directions stated in the technical sheet relative to concentration, temperature and action time.
- Clean the endoscope, while it is immersed in the liquid, with a soft cloth or a sponge proceeding from the proximal end to the distal end until all residues are completely removed.
- Contact time with the cleanser must be at least 5 minutes.

Step 3. Rinsing

- Rinse the instrument with an abundant supply of running water and dry it with a clean cloth/sheet to be changed at every endoscopy. Careful drying must be performed so as to avoid transferring any water thereby diluting the disinfection solution.

Step 4. Disinfection

- Completely immerse the instrument in the disinfectant solution.
- Close the container with a tight lid. The choice of immersion times will follow the guidelines recommended by the technical sheet of the disinfectant in use.

- Test the disinfectant used, if a multipurpose one, at the start of each day to assess the Minimum Effective Concentration (MEC). The results must be documented and the solution must be discarded if the chemical index indicates lower concentrations than the MEC.
- Discard the disinfectant liquid at the end of the period of recommended use regardless of the minimum effective concentration.
- The use of a multipurpose disinfectant does not permit tracking the procedure to check that decontamination was correctly performed.
- Scientific evidence does not suggest particular procedures for immunodepressed patients, for patients with a suspected or verified transmittable infection (e.g. HIV, HCV, TBC, etc.); therefore, it is sufficient to observe good practice for the disinfection of endoscopes.

Step 5. Final rinse

- After disinfection, remove the instrument from the basin, rinsing it thoroughly with sterile water or drinking water that does not contain pathogens (ISO11731, 1998 Water Quality) to remove all disinfectant residues. When using drinking water for rinsing, the user must be aware of the higher risk of recontamination of instruments or equipment with micro organisms that may be present in the water supply. Using a bacteria-retentive filtering system can help to eliminate or considerably reduce the quantity of bacteria transmitted by drinking water.
- The final rinse is an extremely important step because trace residues of disinfectant could cause irritations or damage to the skin and/or mucous membranes of patients and operators.

Step 6. Drying

- Drying must take place by means of a clean cloth/sheet that does not leave dust or filaments. These cloths/sheets must be periodically replaced. The final drying step significantly reduces the possibility of recontamination of endoscopes with micro-organisms that multiply in damp environments.

Step 7. Storage

- If the device is not immediately reused, it is recommended that it be put away in ventilated cabinets built for upright storage to protect it from possible contaminations and from high temperatures.
- In the case of impossibility of putting it away in the appropriate type of cabinet, wrap the instrument in a sterile piece of fabric and place it inside a closed cabinet.
- Storing endoscopes inside carrying cases is not advised owing to difficulties connected with maintaining an adequate level of hygiene along with the risk of their contamination.
- The need to reprocess endoscopic instruments at the start of every day has not been demonstrated if they have been correctly reprocessed and stored within the previous 72 hours.
- If the endoscope must be taken to another unit, a transport procedure is to be implemented that avoids both contamination of the instrument before the endoscopic exam as well as environmental contamination after its use. To this end, containers for

transport must if possible be equipped with a cover, and be of material and dimensions so as to facilitate cleaning and disinfection of the instrument in addition to protecting it during transport.

The manual procedure does not require substantial investment but presents the following disadvantages:

- Risk of errors or forgetfulness on the part of operators leading to the inefficacy of the disinfection procedure;
- Inadequate ability to “track” the procedure;
- Risk of contact between operators and contaminated instruments;
- Risk of environmental contamination;
- Damage to endoscopes;
- Disinfection times of at least 20 minutes, not a negligible problem in view of the intensity and dynamism of activities carried out in an ENT Outpatient facility.

2. Automatic disinfection systems

These are automated systems that disinfect or sterilise the endoscope. Until a little while ago, only washer-disinfector-endoscopes designed for gastroscopies and bronchoscopies were available on the market; today, several firms have made available automatic washer-endoscopes created specifically for non-channelled ENT endoscopes. The automatic systems can be of various configurations:

- Those that automatically cleanse, disinfect and dry without any manual intervention.
- Those that perform only the disinfection step.

The automatic system is composed of:

- A tub for the disinfectant and if applicable one for the cleaning solution;
- A basin with a cover in which the endoscope is positioned for reprocessing. Washer-disinfector-endoscopes in general can reprocess several endoscopes at the same time;
- A panel for setting the washing cycle. All washer-disinfector-endoscopes alternate between disinfection and rinsing cycles. In general, it is possible to set the washing and disinfection sequences in terms of time and temperature according to directions pertaining to the particular disinfectant or sterilizer.

The disinfectant is transferred from the tub to the basin containing the endoscope. After the established exposure time stated on the disinfectant sheet, *the desired degree of disinfection in a certifiable condition is obtained in compliance with the requirements of standard EN 15883*. Once the final rinsing is completed, the endoscope is ready for reuse.

In order to reduce the possibility of contaminations, the washer-disinfector-endoscopes must be in turn regularly disinfected or sterilised. The majority are furnished with thermal auto-disinfection systems.

It is advisable to position washer-disinfector-endoscopes in sufficiently ventilated areas separated from those in which the clinical procedures are carried out.

Upon acquiring a washer-disinfector-endoscope, it is necessary to evaluate with particular attention the following characteristics:

- The possibility of automatically controlling the quantity of cleanser and disinfectant present and loading them automatically;
- The capacity to reprocess more than one endoscope at the same time;

- The ability to program the main functions in terms of sequence, duration and temperature (pre-washing, disinfection, rinsing, drying);
- The possibility of performing a complete cycle of cleansing, disinfection and rinsing;
- Cycle duration;
- The frequency of replacement and cost of filters;
- The type of disinfectants for which the washer-disinfector-endoscope is certified and their cost per cycle;
- The possibility of performing auto-disinfection/auto-sterilization;
- The presence of visual and sound alarms;
- Required space;
- Recording of procedures carried out, an aspect strongly advised today because of medical-legal lawsuits. In general, the data that is recorded and/or printed is:
 - Identification of the instrument that is undergoing reprocessing;
 - Identification of the operator;
 - Operating parameters relative to procedures carried out;
 - Date and time when recording occurs.

The automatic procedure therefore:

- Standardizes the process, avoiding errors or oversights;
- Exposes all components of the endoscope to disinfection;
- Makes it possible to “track” the procedure since most of these types of equipment issue a receipt after every disinfection cycle certifying the positive outcome of the cycle that has occurred. In this way, the quality of service is guaranteed and the operator’s responsibility is defined;
- Reduces the possibility of contact between operators and contaminated instruments;
- Reduces the possibility of environmental contamination;
- Reduces the risk of damage being done to the endoscopes.

Among the disadvantages, one must keep in mind:

- The cost of equipment and maintenance expenses.
Some firms have manufactured specific washer-disinfector-endoscopes for ENT endoscopes, smaller compared with those for gastroenterology, easier to allocate and less expensive (Fig. 1);
- The possibility of recontamination of the endoscopes by the same washer-disinfector endoscope;
- Adequate space to arrange the equipment (often far from the examination site with the ensuing expenditure of time for transport and increase in the possibility of breakage during the trip itself);
- Time required for the disinfection process (in general at least 20 minutes): it was calculated that in order to guarantee the same level of activity compared to manual disinfection systems, about 20 additional endoscopes would have to be acquired.

Below, the steps to follow in the disinfection of endoscopes using automatic systems are described:

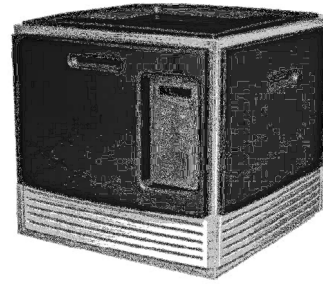


Figure 1. Washer-disinfector-endoscopes dedicated to Otorhinolaryngology.

Step 1. Disconnecting and inspecting the endoscope

- At the end of the endoscopic exam, disconnect the instrument from the light source after turning off the light.
- Clean the endoscope by holding gauze in your hands and wiping the instrument up and down in order to eliminate any adhering organic residues.
- If disinfection occurs in a separate, specific location (which is highly preferable), the transport procedure must prevent contamination of the environment as well as that of health professionals. Containers used for transport must therefore be equipped with a cover and be of material and dimensions so as to facilitate cleaning and disinfection of the instrument in addition to protecting it during transport.
- After reaching the washing room, a leak test is to be conducted before submitting the instrument to disinfection procedures. Using an active and connected tester, tilting motions of the instrument are to be carried out so as to better highlight any areas of damage. Latest-generation washer-disinfector-endoscopes are capable of performing this type of test automatically. If any losses of seal are observed, immediately contact the firm for repairs; a damaged area detected within a short timeframe limits the cost of repair, which rapidly increases if the instrument continues instead to be used.

Step 2. Cleaning with a cleaning solution (if not ensured by the automatic system)

- The purpose is to remove residues of organic and inorganic substances along with micro organisms. The result of a good cleansing action leads to a reduction in microbial contamination, a prerequisite for the successful disinfection of the instrument.
- An enzymatic cleaning solution, which must be changed after every use, is necessary.
- Completely immerse the instrument in the cleaning solution in strict compliance with the directions stated in the technical sheet relative to concentration, temperature and action time.
- Clean the endoscope, while it is immersed in the liquid, with a soft cloth or a sponge proceeding from the proximal end to the distal end until all residues are completely removed.
- Contact time with the cleanser must be at least 5 minutes.
- Some washer-disinfector endoscopes perform this step automatically.

Step 3. Rinsing

- Rinse the instrument with an abundant supply of running water and dry it with a clean cloth/sheet to be changed at every endoscopy. Careful drying must be performed so as to avoid transferring any water and diluting the disinfection solution.

Step 4. Automatic disinfection with washer-disinfector-endoscopes

- Use only those disinfectants specifically indicated by the machine manufacturer of the washer-disinfector-endoscope as compatible with endoscopic instruments.
- Determine and record the MEC daily or weekly if the disinfection activity is occasional. The MEC is identified by means of specific chemical indicators whose purpose is to notify you when it is necessary to replace the disinfectant solution.
- Position the endoscopic instruments in the appropriate basket according to the directions stated in the user's manual and make sure that they are not touching each other.
- Close the lid on the basin and start the selected cycle.
- If the machine is equipped to handle it, always proceed to the drying cycle.
- A weekly disinfection cycle is advisable after prolonged periods of disuse and after any technical assistance.

Step 5. Drying (if it is not performed by the machine)

- Drying must take place by means of a clean cloth/sheet that does not leave dust or filaments. These cloths/sheets must be periodically replaced. The final drying step significantly reduces the possibility of recontaminating endoscopes with micro organisms that multiply in damp environments.

Step 6. Storage

- If the device is not immediately reused, it is recommended that it be put away in ventilated cabinets built for upright storage to protect it from possible contaminations and from high temperatures.
- In the case of impossibility of putting it away in the appropriate type of cabinet, wrap the instrument in a sterile piece of fabric and place it inside a closed cabinet.
- Storing endoscopes inside carrying cases is not advised owing to difficulties connected with maintaining an adequate level of hygiene along with the risk of their contamination.
- The need to reprocess endoscopic instruments at the start of every day has not been demonstrated if they have been correctly reprocessed and stored within the previous 72 hours.
- If the endoscope must be taken to another unit, a transport procedure is to be implemented that avoids both contamination of the instrument before the endoscopic exam as well as environmental contamination after its use. To this end, containers for transport must if possible be equipped with a cover, and be of material and dimensions so as to facilitate cleaning and disinfection of the instrument in addition to protecting it during transport.

Emerging systems

1. Manual disinfection system with wipes

The disinfection system by means of wipes is a comprehensive manual sporicidal disinfection treatment of semi-critical, non-channelled and heat-sensitive medical devices. *Treatment time is only 2-3 minutes.*

The active ingredient used in this high-level disinfection process is chlorine dioxide (ClO_2), patented under the name “Tristel”.

The Tristel Wipe System calls for not only one wipe to be used in the high-level disinfection process, but also a wipe for the pre-disinfection cleaning step and one for the post-disinfection rinsing step. The mechanical scrubbing action increases the efficacy of the cleaning and disinfection steps.

The wipes are single-use and thus permit *tracking* of the decontamination procedure for monitoring its correct execution.

The use of wipes with ClO_2 leads to a notable reduction in disinfection times compared with other disinfectants of equal efficacy used in immersion methods. In addition, they are safe from a health standpoint, since the wipes are non-toxic, non-irritating and non-sensitising.

The steps involved in this disinfection treatment can be outlined as follows:

Step 1. Cleaning

- Cleaning is performed with the Cleansing Wipe (Fig. 2), a non-woven cloth soaked in a solution composed of an enzyme mix (Alcalase, Termamyl and Lipolase), a surfactant and a humectant to remove organic material and prepare the device for the high-level disinfection step.
- Removal occurs by means of the mechanical scrubbing of the instrument. The wipe is laid across the palm of the hand and rubbed along the device using a one-direction manual scrubbing action going from its proximal end to its distal end to physically remove all dirt and visible material. The action is facilitated by the solution contained in the wipe and average performance time is 30-60 sec.
- *It is not necessary to rinse the instrument after cleaning because the residues of the Cleansing Wipe are perfectly compatible with ClO_2 and no excess liquid remains.*
- The wipes are to be kept at a temperature ranging from 10^0 - 35^0 , away from direct sunlight. They are single-use and are to be opened immediately before use and must be disposed of in hospital clinical waste receptacles.
- The use of protective gloves is recommended.



Figure 2. Cleansing wipe.

Step 2. Disinfection

- Disinfection is performed with the Sporicidal Disinfectant Wipe (Fig. 3). Its goal is to eliminate all types of micro organisms. The wipe is a non-woven cloth soaked in an organic acid-based solution (Citric acid, Boric acid, Sorbic acid) to which are applied two doses of the special sodium chlorite-based activation foam (NaClO_2). After squeezing the wipe for 15 seconds, chlorine dioxide is generated. The activated solution is a neutral pH which ensures maximum safety both for the skin as well as for the device.
- The ClO_2 destroys and eliminates all types of micro organisms, including spores, from previously cleaned medical devices.
- The wipe is laid across the palm of the hand and rubbed along the device using a one-direction manual scrubbing action. All parts of the device, including the optical unit, must come into contact with the foamy solution, which is allowed to act for 30 sec.
- The wipes are to be kept at a temperature ranging from 10^0 - 35^0 , away from direct sunlight. They are single-use and are to be opened immediately before use and used immediately after activation.
- The use of protective gloves is recommended.



Figure 3. Disinfectant wipe.

Step 3. Rinsing

- Rinsing is performed with the Rinsing Wipe (Fig. 4), a non-woven cloth soaked in a deionised water solution (sterilized by means of gamma rays) and a small quantity of antioxidant (Sodium thiosulfate) to remove any chemical residues remaining on the device after disinfection.
- The wipe is laid across the palm of the hand and rubbed along the device with a manual scrubbing action for an average time of 30 seconds.
- The rinsing wipe also must be kept at a temperature ranging from 10^0 - 35^0C . It is single-use and is to be opened immediately before use and must be subsequently disposed of in hospital clinical waste receptacles.
- The use of protective gloves is recommended.

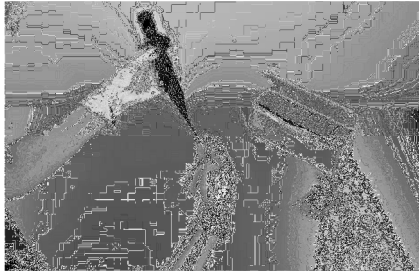


Figure 4. Rinsing wipe.

The Tristel Wipe System was designed for the needs of the ENT Department. It guarantees disinfection at the sporicidal level in timeframes that permit a rapid turnaround of the instrument.

The safe use of ClO_2 enables a manual scrubbing technique not possible with the other traditional high-level disinfectants.

Each treatment wipe is single-use, which allows a tracking system to be put into effect, since every disinfection treatment can be linked to the patient's name.

The system, even if simple to use, is manual and thus can lead to different treatment results from one operator to another: *precise and continuous training is necessary to ensure that all operators responsible for carrying out the disinfection treatment are capable of optimal performance.*

A study²² conducted at an ENT Outpatient facility in an Italian hospital compared the Wipe system with a traditional Immersion system on a sample of 120 cases. The results demonstrated the superiority of the Wipe System in lowering the microbial load, particularly with regard to biofilm-producing micro organisms and bacteria.

2. Immersion disinfection system electronically controlled by a microprocessor

Recently put on the market, this is a high-level disinfection system of semi-critical medical devices sensitive to heat, including ENT endoscopes. The disinfection method is by immersion but is controlled electronically.

The time necessary for disinfection itself is 5 minutes but the overall disinfection treatment time depends on the cleaning method used before disinfection and the rinsing method used at the end of disinfection. The cleaning and rinsing wipes of the Tristel Wipe System could be an option to supplement the disinfection treatment.

The system (Fig. 5) consists of a base unit with a cover, a microprocessor and the disposable, ClO_2 -based high-level disinfectant. After cleaning, the instrument is situated in the special compartment of the base unit to which the disinfectant is added. At the end of the disinfection cycle, the disinfectant is automatically emptied out directly into the sink. The instrument is then rinsed with water of suitable quality.

At the end of the treatment, the base unit can be used as an aseptic container for short-term storage and/or for future transport of the instrument. The base unit and the cover are manufactured from polycarbonate resin and thus are resistant to high temperatures and can tolerate up to 30 autoclave cycles.

The ClO_2 -based disinfectant is capable of destroying all types of micro organisms, including spores. It is packed in envelopes with two compartments that are separated by a thin membrane

and which contain the two precursor solutions: 50 ml of sodium chlorite solution and 50 ml of organic acid solution. Handling the envelope breaks the membrane and allows the two solutions to mix together. After about 30 seconds, a concentrated single-use solution of ClO_2 is generated. The solution is diluted in 5 litres of cold water and then poured into the base unit holding the previously cleaned instrument. Studies demonstrate that the level of ClO_2 present in the disinfectant solution is a valid substitute for glutaraldehyde^{23 24}.

The microprocessor monitors and records every disinfection cycle and issues a validation code at the end of the successful cycle, making it possible to *track* the entire process. By means of the display, the operator is guided throughout all the steps of the disinfection cycle. A sensor automatically begins the contact time (5 minutes) when the compartment of the base unit is full of 5 litres of disinfectant. If the level of disinfectant was not adequate, the cycle is not validated. At the end of 5 minutes, the sensor gives instructions on how to open the unit valve and empty out the used disinfectant, thus avoiding any risk of overexposure of the instrument to the disinfectant. The cycle is finished by a rinse. The validation code generated at the end of the cycle is indicated on the display and registered in the memory together with all the significant events of the disinfection cycle. All the recorded data can be downloaded on to the PC and archived.

The sequence of operations to follow is devised so as to eliminate any form of contact between the operator's skin and the disinfectant: the instrument is situated in the empty unit and removed only when the disinfectant is emptied out.

The system can also be placed on a cart in a manner that makes it easily transportable. In fact, no connection to the electrical network is necessary because the system is powered by rechargeable batteries and the only installation requirement is its close positioning to a sink in order to empty out the used disinfectant.

The immersion system with electronic control is an important evolution compared with the traditional manual immersion system using a tray since, although it doesn't have all the characteristics of automated systems, by means of the microprocessor, contact time is guaranteed and potentially damaging chemical overexposure of the instrument is avoided, in addition to the ability to track the entire procedure. While investment and management costs are less in comparison with the automatic system, the qualitative level of disinfection is perfectly adequate.



Figure 5. Immersion disinfection system electronically controlled by a microprocessor.

3. *Sterile protective encasing*

This is an endoscope encasing system that can represent an alternative to the high-level disinfection of endoscopes (Fig. 6).

It must however be emphasized that various studies^{25 26} have demonstrated *the necessity to clean the entire endoscope (including the optical unit) with an enzymatic cleanser, followed by a medium-level disinfectant with 70% ethanol* immediately after the removal of the encasing and before fitting the next one, in order to guarantee the equivalent of a high-level disinfection. Small viruses in fact are capable of penetrating the encasing and remaining on the surface of the instrument.

From the investigation conducted at Hospital ENT Departments, it was ascertained that the practice of cleaning and disinfecting is done in only 2% of cases after removal of the encasing.

The advantage of this system is the *speed* with which the endoscope is ready again for a new exam. *The disadvantages* are represented by:

- An increase of the diameter of the endoscope with the subsequent greater likelihood of discomfort for the patient;
- The optical unit is unprotected against contamination;
- The possibility of breakage of the encasing during the exam (cases were reported of the tip of the encasing detaching and getting stuck in the patient's airways)²⁷;
- The possibility of damage to the endoscope when removing the encasing;
- Vision is not optimal;
- Costs: endoscopes of various brands moreover require specific encasings.

To recall:

- The choice of the disinfection system is made in consultation with the Director of the Unit, the Pharmacy Service, the Committee assigned the task of infection control of the member Local Health Unit and the directions of the endoscope manufacturer;
- Endoscopes that cannot be totally immersed are replaced;
- Instruments are promptly treated after use since if left dry for a long period, residues can harden causing encrustations and damage to the instruments themselves;
- If endoscopes are left immersed in liquid for a long period, the seals can deteriorate;
- The endoscopic exam should be avoided in patients with a suspected variant of Creutzfeldt-Jacob disease (resistant to all conventional forms of sterilization).

If an endoscopy is deemed essential, a dedicated endoscope must be used or an instrument at the end of work activity. After use, the endoscope must be placed in quarantine until the definitive confirmation of the pathology (which occurs with the autopsy exam)³¹.

Disinfection of endoscopes contaminated with the Hepatitis B, Hepatitis C or HIV viruses or mycobacteria^{28 29}

At the present time, there have been no reports of virus transmission through bronchoscopes whereas cases of the transmission of Hepatitis B and C through gastroscopes have been documented and concern inadequately disinfected instruments.

The majority of viruses, including Hepatitis and HIV, are rapidly neutralized with disinfectant solutions. The greatest risks of viral transmission reside in the failure to remove biological residues by means of manual cleaning, thus allowing the viruses to evade contact with the disinfectant.

Mycobacteria were responsible for a higher percentage of the contamination episodes reported in the literature. The cases of tuberculosis were attributed to the failure to observe at least one of the infection control procedures.

Although several authors have upheld the need to lengthen the disinfection times of endoscopes after use in patients affected by mycobacteria, this strategy is not necessary if the current Guidelines for infection control are attentively followed. Numerous studies have shown for example that with immersion in an alkaline solution of 2% glutaraldehyde at 20⁰C for 20 minutes, after sufficient cleaning, a major reduction of the bacterial load of *Mycobacterium tuberculosis* is obtained.

Disinfection of endoscopes contaminated by prions³⁰⁻³⁴

Prions are responsible for transmissible spongiform encephalopathies (TSE), capable of causing degenerative diseases of the central nervous system in animals and in humans.

The most frequent disease from prions is Creutzfeldt Jakob Disease (CJD); other forms are Kuru (cannibalism, New Guinea), Gertsmann Strausler Scheinker (GSS), Fatal Familial Insomnia (FFI) and Variant CJD (vCJD).

Prions are resistant to common disinfectant substances. Tissues at high risk of infection are the brain, dura mater, spinal cord and eyes, while tissues at low risk are CSF (cerebrospinal fluid), liver, lymph nodes, kidneys, lungs and spleen. However, no reported cases of CJD were attributed to devices contaminated with blood.

Cases of CJD recognized as iatrogenic were attributed to contaminated medical devices such as brain electrodes, brain neurosurgical instruments, dura mater grafts, corneal grafts, gonadotropins and human growth hormones.

From the analysis of the literature, it was concluded that *endoscopes (except neurosurgical ones) are devices that normally do not come into contact with tissues at risk of TSE* and thus, even when they are used for diagnostic procedures in high-risk patients, standard treatment protocols are adequate.

That does not remove the first and foremost preventive measure to take in the case of high-risk patients, that of *limiting endoscopic procedures exclusively to those that are necessary. If actually necessary, it is advised to designate one endoscope for these patients even for future use.*

In the case of endoscopic procedures that require contact with low- and high-risk tissues in patients with probable or confirmed TSE, the Guidelines of the World Health Organization establish special treatments (Sodium Hydroxide, Sodium, Hypochlorite Phenol, Autoclave sterilization) not tolerated by endoscopes.

Since the disinfectants most commonly used for endoscopes are ineffective, considering the high cost of these instruments, some Authors suggest *covering the endoscope with a plastic encasing*, eliminated as special waste, to serve as protection of the endoscope, only partial however.

Moreover, ENT endoscopic procedures can be handled without any special precaution, since the tissues with which they come into contact are not considered infectious.

In these patients, *the standard protocols of cleaning and high-level disinfection are adequate.*

Biological controls

Many aspects of the endoscope disinfection process lend themselves to the monitoring of quality controls, but none of these can be sufficiently fine-tuned so as to ensure that the disinfection treatment has indeed removed all contaminants. In addition, monitoring infections resulting from endoscopic procedures cannot be a tangible and practical indicator of the efficacy of disinfection since infections are rarely detected and linked to the execution of the endoscopic exam performed.

For these reasons, the scientific community questions whether or not it is appropriate to out routine culture tests on endoscope surfaces. Moreover, the culture methods currently in use to monitor outcomes have not been rigorously validated, with the danger of underestimating results (false negatives) or overestimating results (false positives), consequently causing potential harm to patients and health facilities³⁵.

In the absence of adequate scientific evidence, the Guidelines send mixed messages with regard to conducting microbiological tests on endoscopes.

The APIC (Association for Professionals in Infection Control and Epidemiology) and the CDC (Centres for Disease Control and Prevention) do not recommend routinely conducting microbiological tests and advise them *only in cases of epidemics*. Our working group is in agreement with this decision.

Tracking systems⁵

In every unit where endoscopic exams are performed, a system recording all procedures conducted must be in place.

The following must be assigned to each procedure performed:

- Sequence number;
- Patient's first and last name and date of birth;
- Description of procedure and date carried out;
- Data identifying the doctor;
- Endoscope identification number;
- Type of disinfection implemented and Person in charge.

The nursing coordinator of the unit must maintain:

1. Documentation relative to installation, testing and ordinary/special maintenance of the washer-disinfector-endoscope machines (for the entire time the machine is in use and for 5 years following end of service);
2. User's manuals for all the equipment and fittings/devices of all the endoscopes;
3. Documentation relative to biological controls carried out on the washer-disinfector-endoscope machines and on the endoscopes themselves (at least 5 years);
4. A copy of the print-out issued by some of the washer-disinfector-endoscopes, certifying the successful outcome of the disinfection cycle (at least 5 years);
5. Log of actions/interventions (unlimited time).

Conclusions

General norms:

1. Each patient must be considered a potential source of infection and therefore every test and every cleaning and disinfection procedure must be performed with the utmost rigour and consistency.
2. The nursing staff as well as the doctor using the endoscope are responsible for the endoscope disinfection process.
3. The choice of disinfectant solutions is made by the Director of the Unit in consultation with the Pharmacy Service and the Committee assigned the task of infection control of the member Local Health Unit.
4. The staff must wear individual protective gear during the performance of the endoscopic procedure and throughout the various steps of disinfection of the instruments.
5. A distinct division must exist between cleaned and contaminated areas.
6. Disinfection must be carried out by adequately trained staff with periodic checks of their skill levels and competence.
7. Periodic microbiological controls are not recommended as indicators of the quality of the disinfection process. If a contamination is suspected, culture tests on endoscopes, on tap water and on disinfection treatment instruments should be conducted.
8. In the case of a suspected or confirmed infection, consult the Committee assigned the task of infection control of the member Local Health Unit.

Disinfection steps:

1. After every endoscopic exam, the leak test and visual inspection of overall integrity and good condition of the instrument must occur before it undergoes disinfection.
2. Endoscopes that cannot be totally immersed must be replaced.
3. Before using cleansing solutions and/or disinfectants, read the technical sheet and the safety sheet: observing concentration, temperature and contact time limits ensures obtaining effective disinfection.
4. A thorough cleaning of the instrument (immediately after use) with a cleaning solution to remove organic material is fundamental for obtaining proper disinfection.
5. Disinfectants must be registered by the Ministry of Health with the requirement that the registration indicates methods of use, concentrations, contact times, temperature and pH.
6. If the disinfectant is a multipurpose one, it is necessary to:
 - a. Test the MEC of the disinfectant at the start of every work day. The results must be documented and the solution must be emptied out if the concentrations are lower than the minimum effective concentration;
 - b. Discard the disinfectant liquid at the end of the recommended period of use regardless of the minimum effective concentration.
7. Dry the endoscope before storing it. Dampness can increase the risk of infection.
8. Keep a log recording the use of endoscopes along with the management and disinfection of washer-disinfector-endoscopes, if there are any.

Disinfection systems:

The ideal disinfection system is the one that enables:

- *Standardization of the process, avoiding errors or oversights;*
- *Rapid turnaround of endoscopes;*

- *Tracking ability to ensure quality of performance;*
- *Reduction of risks of operator contamination;*
- *Reduction of risks of damage to endoscopes.*

In relation to these ideal characteristics, we will summarize here the advantages and disadvantages of the various disinfection systems in such a way that a choice can be made selecting the ideal system closest to the reality and specific characteristics of the actual situation (human and economic resources, spaces available, activity volumes, number of endoscopes).

1. The manual immersion method does not require major investment but poses the following disadvantages:
 - Risks of errors and/or omissions;
 - Inadequate “tracking”;
 - Risk of operator contamination;
 - Risk of environmental contamination;
 - Damage to endoscopes;
 - Disinfection times of at least 20 minutes.
2. The automatic system:
 - Standardizes the process avoiding errors or oversights;
 - Permits “tracking” the procedure;
 - Reduces the possibility of contact of operators with contaminated instruments;
 - Reduces the possibility of environmental contamination;
 - Reduces the risk of damage to endoscopes.

Among the disadvantages:

- Cost of equipment/fittings and maintenance costs;
- Adequate space to arrange the equipment (often far from the examination site with the ensuing expenditure of time for transport and increase in the possibility of breakage during the trip itself);
- Time required for the disinfection process (in general at least 20 minutes). Adding this time to the transport time, the endoscope becomes ready in one hour’s time.

Some firms have manufactured washer-disinfector-endoscopes specific for ENT endoscopies, smaller compared to those used for gastroenterology, easier to allocate and less expensive.

3. The wipe system with ClO₂:
 - Allows rapid turnaround of the instrument (less than 5 minutes);
 - Enables tracking, since the wipes are single-use.

This is a manual system and therefore the continuous and precise training of staff is indispensable.

4. The immersion system with electronic control:
 - Guarantees contact time avoiding potentially damaging chemical overexposure of the instrument;
 - Permits tracking;
 - Acquisition and management costs are less compared with the automatic system.

The pre-disinfection and cleaning steps as well as the rinsing step are manual and thus require exercising maximum caution.

5. Sterile protective encasing:

Allows for a rapid turnaround of the instrument but its correct use requires cleaning and disinfection after it is removed.

The disadvantages are represented by:

- Possibility of discomfort for the patient;
- Optical unit is unprotected from contamination;
- Possibility of breakage of the encasing during the exam;
- Possibility of damage to the endoscope when removing the encasing;
- Vision is not optimal;
- Costs.

Bibliography

- 1 American Society for Gastrointestinal Endoscopy (ASGE). *Technology Assessment Committee Position Paper. Transmission of infection by gastrointestinal endoscopy*. Gastrointest Endoscopy 1993, pp. 885-8.
- 2 Birnie GC, Quigley A, Clements GB, et al. *Endoscopic transmission of hepatitis B virus*. Gut 1983;24:171-4.
- 3 Bronowicki JP, Venard V, Botte C. *Patient-to-patient transmission of hepatitis C virus during colonoscopy*. N Engl J Med 1997;337:237-40.
- 4 Morris J, Duckworth GJ, Ridgway GL. *Gastrointestinal endoscopy decontamination failure and the risk of transmission of blood-borne viruses: a review*. J Hospital Infection 2006;63:1-13.
- 5 Agenzia Sanitaria Regionale dell'Emilia-Romagna. *Reprocessing degli endoscopi. Indicazioni operative*. Dossier 133, Bologna 2006.
- 6 CCLIN Sud-Ouest-Centre de coordination de lutte contre les infections nosocomiales. *Prévention du risque infectieux en imagerie médicale non interventionnelle*. Bordeaux 2004.
- 7 Culver DA, Gordon SM, Mehta AC. *Infection Control in the Bronchoscopy Suite*. Am J Respir Crit Care Md 2003;167:1050-6.
- 8 Rutala WA, Weber DJ. *Reprocessing endoscopes: United States perspective*. J Hosp Infect 2004;56(Suppl 2): S27-39.
- 9 Spaulding EH. *Chemical disinfection of material and surgical materials*. In: Block SS, ed. *Disinfection, sterilization and preservation*. Philadelphia: Lea & Febiger; 1968, pp. 617-41.
- 10 CDC. *Guideline for Disinfection and Sterilization in Healthcare Facilities*. University of North Carolina, Chapel Hill; 2008.
- 11 CDC. *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. University of North Carolina, Chapel Hill; 2004.
- 12 Alvarado CJ, Reichelderfer M, and the 1997, 1998, 1999 APIC Guidelines Committees. *APIC Guideline for infection prevention and control in flexible endoscopy*. Am J Infect Control 2000;28:138-55.
- 13 APIC – *Guideline for infection prevention and control in flexible endoscopy*. Am J Infect Control 2000;28:138-55.
- 14 Australian Government. Department of Health and Ageing. *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*. Canberra; 2004.
- 15 British Society of Gastroenterology. *Guidelines for decontamination of equipment for gastrointestinal endoscopy*. London; 2003.
- 16 British Society of Gastroenterology (BSG). *Gastrointestinal Endoscopy Equipment Evaluation and Procurement. A guide to the process*. London; 2005, pp. 9,54-5.
- 17 Darbord JC. *Importance of Cleaning for reprocessing endoscopes and thermolabile steril medical devises: French use and regulation*. J Hosp Infect 2004;56:40-3.

- 18 ESGE/ESGENA. *Technical Note on Cleaning and Disinfection*. *Endoscopy* 2003;35:869-77.
- 19 Lim M, Gupta D. *Flexible naso-endoscopic decontamination- rationalizing the next step forward*. *J Hosp Infect* 2006;62:136-40.
- 20 Nelson DB, Jarvis WR, Rutala WA, et al. *Multi-society guideline for reprocessing flexible gastrointestinal endoscopes*. *Dis Colon Rectum* 2004;47:413-20.
- 21 Beilenhoff U, Neumann CS, Biering H, et al. *ESGE/ ESGENA guideline for process validation and routine testing for reprocessing endoscopes in washerdisinfectors, according to European Standard prEN ISO 15883 parts 1,4 and 5*. *Endoscopy* 2007;39:85-94.
- 22 Fontanot M, Fontana F, Bon L. *Tecniche microbiologiche nella comparazione di due metodi per la disinfezione ad alto livello di naso endoscopi*. Facoltà di Medicina e Chirurgia dell'Università degli Studi di Trieste (comunicazione personale).
- 23 Isomoto H, Urata M, Kawazoe K, et al. *Endoscope disinfection using chlorine dioxide in an automated washer-disinfector*. *J Hospital Infection* 2006;63:298- 305.
- 24 Coates D. *An evaluation of the use of chlorine dioxide (Tristel One-Shot) in an automated washer/disinfector (Medivator) fitted with chlorine dioxide generator for decontamination of flexible endoscopes*. *J Hospital Infection* 2001;48:55-65.
- 25 Alvarado CJ, Anderson AG, Maki DG. *Microbiological assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing: a prospective clinical trial with nasopharygoscopes*. *Am J Inf Control* 2009;37:408-13.
- 26 Baker KH, Chaput MP, Clavet CR, et al. *Evaluation of endoscope sheaths as viral barriers*. *Laryngoscope* 1999;109:636-9.
- 27 Awad Z, Pothier DD. *A potential danger of flexible endoscopy sheaths: a detached tip and how to retrieve it*. *J Laryngol Otol* 2009;123:243-4.
- 28 Martin YH, Floss H, Zuhlsdorf B. *The importance of cleaning for the overall results of processing endoscopes*. *J Hosp Infect* 2004;56(Suppl 2):S16-22.
- 29 Schembre DB. *Infectious complications associated with gastrointestinal endoscopy*. *Gastrointest Endosc Clin N Am* 2000;10:215-31.
- 30 Ippolito G, Petrosillo N, Suzzi R. *Rischio di trasmissione iatrogena e nosocomiale dell'agente della malattia di Creutzfeldt-Jakob e misure di prevenzione*. *GIIO* 1997;4.
- 31 Ministero della Sanità 2 dicembre 1996. *Linee guida e norme di sicurezza da osservare in caso di riscontro autoptico su soggetti con probabile malattia di Creutzfeldt Jacob o sindromi correlate*.
- 32 Rutala W, Weber D. *Creutzfeldt Jakob Disease: recommendations for disinfection and sterilization*. *Clin Infect Dis* 2001;32:1348-56.
- 33 Legnani P, Fagioli A, Leoni E. *Encefalopatie spongiformi trasmissibili (EST). Misure di prevenzione per il controllo delle infezioni iatrogene*. *GIIO* 2001;8.
- 34 OMS World Health Organization. *Infection control guidelines for transmissible spongiform encephalopathies*. 2000.
- 35 Beilenhoff U, Neumann CS, Rey JF, et al. *ESGE-ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy*. *Endoscopy* 2007;39:175-81.

The disinfectants for the reprocessing of heat sensitive non lumened ENT Endoscopes

M. Cavaliere, M. Iemma

Struttura Complessa di Otorinolaringoiatria, Azienda Ospedaliera Universitaria “San Giovanni di Dio e Ruggi d’Aragona”, Salerno

SUMMARY

The disinfection is performed with a wide variety of disinfectants and from an analysis of the various solutions on the market, we have noticed that not all the products used are tested according to current norms (EN 14885) and that different contact times are indicated for the same product. Consequently, we have decided to present the most currently used disinfectants for the reprocessing of ENT endoscopes, indicating for each Characteristics, Mode of action, Spectrum of action, Compatibility with materials, Toxicity/Precautions for use, Disposal and Indications of use.

In this way, we have attempted to provide a tool which allows everyone to select the disinfectant which corresponds most closely to their working needs in terms of quality of the disinfection process and the number of procedures to perform.

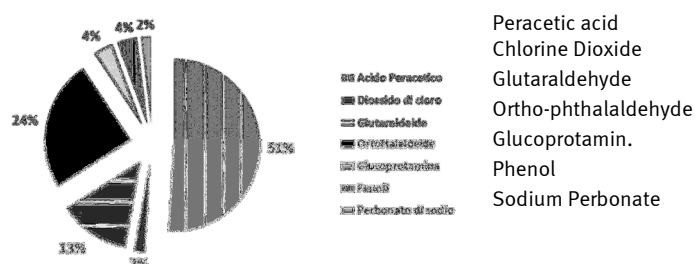
KEY WORDS: Heat-sensitive ENT endoscopes • Cleaning • Disinfection Introduction

Introduction

A survey conducted at Italian Hospital Otorhinolaryngology (ENT) Departments (Fig. 1) showed that *ortho-phthalaldehyde* solution and the prepared solution of *peracetic acid* are becoming more and more widespread with respect to 2% glutaraldehyde not because of the efficacy of disinfection but because of problems related to the health of operators. A disinfectant that was recently re-evaluated using different methods of use with respect to those established previously is *chlorine dioxide*. Another substance used in various situations is *glucoprotamin*.

Within the same Health Facility, different disinfectant solutions often exist and are used to disinfect the same type of endoscope with the use of one solution versus another depending on the Unit.

Before entering into a description of the principal disinfectant solutions, it is necessary to reiterate the following points regarding their choice and use¹².



[Figure 1] Disinfectants used at Italian Hospital Otorhinolaryngology (ENT) Departments for reprocessing endoscopes by immersion.

1. The disinfectants must be registered by the Ministry of Health and their relative technical sheet must indicate first:
 - Methods of use;
 - Concentrations;
 - Contact times;
 - Temperature;
 - pH.
2. Choose the disinfectant compatible with the endoscope, according to the indications of the instrument manufacturers.
3. The identification and selection of solutions is made in consultation with the Pharmacy Service, the Health Department and the Directors of the Unit involved.
4. The disinfectant solutions in use must be managed and stored in such a way as to avoid their possible contamination (for example, containers handled with dirty hands and gloves, partial closure of packaging, etc.).
5. If the disinfectant is reused multiple times, it is necessary to:
 - Test the disinfectant being used at the start of every work day to evaluate the Minimum Effective Concentration (MEC). The results must be documented and the solution must be discarded if the chemical index demonstrates concentrations lower than the MEC.
 - Discard the disinfectant liquid at the end of the period of recommended use without paying attention to the minimum effective concentration. If disinfectant is added to the washer-disinfector endoscope, determination of the expiry date must be based on the original preparation.

Disinfectant solutions

Below are the monographs of the most frequently used chemical solutions *according to the information furnished by the manufacturers and the data from the scientific literature.*

Glutaraldehyde (for example Cidez, Asep, basic Glutaster, Sporex)³⁴

Active ingredient

Glutaraldehyde or glutaric aldehyde in an aqueous solution has the appearance of a clear, colourless or pale yellow liquid, with a pungent odour. The solution most used is a 2% alkaline solution.

Characteristics

Glutaraldehyde is marketed especially in its acid form, which remains stable for long periods of time when it is kept cool in tightly-shut containers (up to 5 years).

Before use, glutaraldehyde *must be "activated"*, by adding a buffer and a surfactant in order to reach a pH level of 7.5-8.5. The activator is separate (e.g. bicarbonate) so as to obtain extemporaneously the basic solution which is characterized by a *stability of 14 days*.

This period of validity refers to the activated solution in its original bottle, whereas the period of reusability must be defined in accordance with the concentration one wants to take as the limit

of activity, generally not less than 1.5% (the concentration diminishes with time and with the number of decontaminating interventions).

Mechanism of action

Glutaraldehyde is also defined as glutaric dialdehyde, because it contains two aldehyde groups (CHO), positioned at the end of the molecule, which are the real reasons for its biocidal action: they are directly involved in the alkylation of sulphide, carboxyl, amine and hydroxyl groups of the proteins from micro organisms, with irreversible alteration of protein synthesis and nucleic acids.

Glutaraldehyde is not significantly inactivated by the *organic material* even its *presence renders disinfection less effective* because of the fixative power of glutaraldehyde which is capable of creating a protective sleeve, impeding the destruction of microbial cells. In fact, it is widely known that glutaraldehyde is not effective against biofilm.

Spectrum of action

The spectrum of action of glutaraldehyde is almost complete but contact times vary greatly according to conditions: for example, at 2% in the laboratory, it is active in:

- 1-2 minutes against bacteria in vegetative form (among which *Staphylococcus aureus*, including the penicillin-resistant strains, *Pseudomonas aeruginosa*, *Escherichia coli*);
- 5-10 minutes against viruses (i.e., Polio I, Coxsackie B1, ECHO 6, Rotavirus, HAV, HBV, HCV, HTLV-III/LAV);
- 10 minutes against yeasts, dermatophytes and moulds (among which *Trichophyton interdigitalis*, *Microsporum gypseum*, *Candida albicans*, *Aspergillus niger*);
- 20 minutes on *Mycobacterium tuberculosis* whereas with respect to other mycobacteria, activity is slower (at least 60 minutes) because of the lipid component of their wall that confers on them a sort of impermeability. Activity increases and thus times are reduced if a solution at 3-4% is used and/or if the ambient temperature exceeds 25°C;
- 3 hours on spores. Concentrations lower than 2% do not offer guarantees of good sporicidal effect, not even at prolonged times.

Compatibility with materials

Glutaraldehyde is not corrosive on metals nor does it pose particular problems for rubber, plastic, glass and optical fibres. However, it is necessary to take some precautions:

- Objects made of steel and carbon must not remain in contact with the solution for more than 24 hours;
- It is essential to avoid contact between instruments made of different metals in immersion (danger of electrolyte reactions capable of corroding the instruments themselves).

Toxicity/precautions

Glutaraldehyde is a toxic substance, an irritant and a sensitising agent and can cause, in the case of insufficient rinsing, rhino conjunctivitis, asthma, diarrhoea and abdominal cramps.

However, the main problem associated with glutaraldehyde's toxicity concerns the trained staff using it, because:

- Frequent contact with the skin can cause dermatitis and persistent brown or yellow skin coloration;
- Contact with the eyes can cause reddening of the conjunctiva and possible serious injuries to the cornea;
- Exposure to its fumes can cause:
 - Irritation of the conjunctiva with stinging, tearing and reddening;
 - Damage to the respiratory tract with bronchitis, dyspnoea and bronchial asthma;
 - Damage to the central nervous system with headaches and depression;
- Ingestion can cause moderate to significant irritations of the mouth, throat, oesophagus and abdomen, chest and stomach pains, nausea, vomiting, diarrhoea, dizziness, drowsiness and shock.

As far as continued exposure is concerned, the product is not carcinogenic, by inhalation, on laboratory animals.

The literature reports a TLV/TVA* value from 0.2 to 0.05 ppm.

For these reasons, *use of glutaraldehyde must:*

- *Provide for the use of appropriate personal protective equipment:*
 - Protective goggles;
 - Approved respirator with a filter for organic fumes, only in the presence of elevated fume concentrations;
 - Protective shirt;
 - Gloves in butyl or nitrile or a double pair of latex gloves;
- *Provide for use in ventilated environments, in closed containers and in the presence of suitable suction and blowing systems;*
- Provide training to the assigned staff about the correct methods of use and furnish toxicity information.

In the case of exposure, *first aid measures* will vary based on the area affected:

- Contact with the eyes: wash thoroughly with water for at least 10 minutes. Remove contact lenses if it is possible to do so easily. Visit an eye specialist;
- Contact with the skin: remove contaminated garments and wash affected skin areas with soap and water. Consult a doctor if irritation persists;
- Ingestion: the product can cause ulceration and inflammation of the upper digestive tract; it is preferable, therefore, not to induce vomiting but to use a safe gastric lavage;
- Inhalation: transfer the subject into a ventilated area. It may be necessary to use artificial respiration.

The use of glutaraldehyde as a high-level disinfectant is in constant decline, not so much owing to reasons of efficacy, but rather because of health issues affecting the operators who must use it⁴.

* Threshold Limit Value-Time Weighted Average: average concentration of a chemical agent weighted on a work exposure of one workday of 8 hours and for 40 hours of work per week, to which operators can be exposed without manifesting adverse health symptoms.

Disposal

In the initial concentration (2%), glutaraldehyde is possibly “harmful”. However, this percentage progressively diminishes owing to the effects of reuse, evaporation and gradual dilution.

According to Italian legislation, which has transposed the regulations of the European Community, disposal of used solutions is allowed with sinks, considering the strong diluting effect at work of the water used daily for hospitalised patients, given that sinks are employed in well-ventilated areas and water is being constantly run to accelerate outflow. However, attention must be paid to avoid the direct disposal of large quantities into the drainage system owing to the potential damage to purification systems because of the inhibition of bacterial activity.

Indications for use

2% glutaraldehyde is indicated for the high-level disinfection of endoscopes and semi-critical medical devices for a contact time not less than 20 minutes at a temperature of 20°C or higher.

For bronchoscopes, a contact time of 1 hour is advised because in terms of mycobacteria, activity is slower. Sporicidal activity can on the other hand be deemed satisfactory after three hours of contact.

In studying residual glutaraldehyde on plastics and rubber, after treatment in a 2% glutaraldehyde solution, it was concluded that a *2-minute rinse* is sufficient to significantly reduce the quantity of the active ingredient absorbed on the surface of the exposed material, with the exception of natural rubbers, for which prolonged soaking and rinsing times are recommended³⁴.

Ortho-phthalaldehyde (for example Cidex OPA, Opaster)⁶⁻⁸

Active ingredient

It is an aromatic dialdehyde which has been on the market a few years even in Italy and is used generally at a *concentration of 0.55%* in an aqueous base. It presents a slightly accentuated odour and is of a light blue colour and is stable at 15-30°C for two years.

Characteristics

Unlike glutaraldehyde, ortho-phthalaldehyde *is already ready for use*, not requiring activation. Once open, the unused solution can be preserved in the original bottle for about 2 months while the solution that was poured into the other container for disinfection can be *used for a period not greater than 14 days*, as long as the concentration of ortho-phthalaldehyde is higher than the minimum effective concentration (at least 0.3%) indicated by the special reaction strips. Once 14 days have passed, the product must in any case be thrown away, even if the concentration is still higher than the minimum effective concentration.

Mechanism of action

In the case of bacteria, ortho-phthalaldehyde causes the formation of crosslinks between the lipoproteins of the cytoplasmic membrane with a consequent cementing effect on the external layer of the cell and limitation of exchanges. The periplasmic enzymes are moreover inactivated with the ensuing rapid death of the cell.

In the case of yeasts and moulds, the principal site of interaction is the chitin, the principle component of the cell wall, as well as the surface enzymes present on the cell membrane. Like glutaraldehyde, ortho-phthalaldehyde is not effective against biofilms.

Spectrum of action

Ortho-phthalaldehyde is capable of exercising a rapid disinfectant action in barely 5 minutes at ambient temperature (20°C) on the majority of micro organisms tested, with the exception of spores, for which higher concentrations at much greater temperatures (1% for 10-12 hours or 0.55% for 24 hours) are necessary.

Specifically, in the laboratory, it acts in:

- 5 minutes against bacteria in vegetative form (among which *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Enterococcus*, *Escherichia coli*);
- 5 minutes against viruses (Adenovirus, Coxsackie virus, Citomegalovirus, *Herpes simplex*, HIV-1, human Corona virus, Type A Influenza, Polio, Rhino virus);
- 5 minutes against yeasts, dermatophytes and moulds (*Candida albicans*, *Aspergillus niger*, *Trichophyton mentagrophytes*);
- 5 minutes on *Mycobacterium bovis*, *M. avium*, *M. terrae*, *M. smegmatis*;
- 10 hours on the spores of *Clostridium difficile* and *Bacillus subtilis*.

Compatibility with materials

The Solution of ortho-phthalaldehyde was shown to be compatible with a wide range of materials commonly used in the manufacture of medical instruments able to be reprocessed (metal, plastic, elastomers and adhesives) and, in many cases, it proved to be less aggressive than glutaraldehyde-based products. *Endoscopic instruments underwent testing and were deemed compatible with the solution.* For extended contact times (greater than 15 minutes), ortho-phthalaldehyde can permanently colour the substrates with which it comes into contact.

Toxicity/precautions

Ortho-phthalaldehyde is a much less volatile molecule than glutaraldehyde and its toxicity, although targeting the same organs as glutaraldehyde, is of minor importance.

Exposure to ortho-phthalaldehyde causes different effects according to the type of contact:

- Ingestion can cause irritation of the pharynx, oesophagus and stomach with nausea, vomiting and diarrhoea;
- Skin contact can cause temporary spots and slight irritations, especially after prolonged exposure. The symptoms generally disappear when exposure ends;
- Eye contact can cause spots, excessive tearing and conjunctivitis;
- Inhalation: ortho-phthalaldehyde is not considered volatile and risks of inhalation are not considered to exist during normal use. However, exposure to the spray or particulates can lead to mild irritation of the respiratory passages with coughing and sneezing. Symptoms are generally alleviated when exposure ends.

This product does not produce mutagenic embryo toxic or teratogenic effects in humans. Its components are not considered carcinogenic.

Occupational exposure limits, however, have not been established.

Thus, as for glutaraldehyde, *the use of ortho-phthalaldehyde must also:*

- *Provide for the use of appropriate personal protective equipment:*
 - Protective goggles;
 - Approved respirator with a filter for organic fumes, *only in the presence of elevated fume concentrations*;
 - Protective shirt;
 - Gloves in butyl or nitrile or a double pair of latex gloves;
- *Provide for use in ventilated environments, and in closed containers* (if these requirements are met, suction and blowing systems are not necessary);
- Provide training to the assigned staff about the correct methods of use and furnish toxicity information.

In the case of exposure, the same *first aid measures* specified for glutaraldehyde are valid, namely:

- Contact with the eyes: wash thoroughly with water for at least 10 minutes. Remove contact lenses if it is possible to do so easily. Visit an eye specialist;
- Contact with the skin: remove contaminated garments and wash affected skin areas with soap and water. Consult a doctor if irritation persists;
- Ingestion: the product, if ingested, can cause ulceration and inflammation of the upper digestive tract; it is preferable, therefore, not to induce vomiting but to use a safe gastric lavage;
- Inhalation: transfer the subject into a ventilated area. It may be necessary to use artificial respiration.

Disposal

According to Italian legislation, as for glutaraldehyde, disposal of used solutions is allowed with sinks, considering the strong diluting effect at work of the water used daily for hospitalised patients, given that sinks are employed in well-ventilated areas and water is constantly being run to accelerate outflow. However, attention must be paid to avoid the direct disposal of large quantities into the drainage system owing to the potential damage to purification systems because of the inhibition of bacterial activity.

Indications for use

0.55% ortho-phthalaldehyde is indicated for the high-level disinfection of endoscopes and semi-critical medical devices for a contact time of at least 5 minutes at a temperature of 25⁰C in an automatic washer-disinfector endoscope and 12 minutes at a temperature of 20⁰C with the manual method.

A rinse of at least 1 minute with plenty of water is sufficient to remove any trace of the disinfectant.

Peracetic acid (for example Nu Cidex, Steris, Persafe, Gigasept, Dopsidex, Adaspor, Oxydrox, Perax liquid, Steradrox, Anioxide, SP3)^{®9}

Active ingredient

Peracetic acid solutions are aqueous solutions, of pungent odor, colourless or pale yellow, with a pH of about 6, containing in dynamic equilibrium peracetic acid, hydrogen peroxide and acetic acid.

Currently, in the health field, peracetic acid solutions are differentiated as follows:

- Extemporaneously diluted from concentrates;
- Prepared extemporaneously from automated systems that control the variables (dilution, temperature, contact times, pH, etc.);
- Prepared in the final concentration (0.35%).

Characteristics

Peracetic acid is by itself an unstable compound and thus it will be necessary to preserve the concentrated solutions in closed bottles, preferably kept cool. *Diluted solutions must be prepared extemporaneously and their validity can range from 1 hour to 12 days* depending on the type of dilution, the cleaning and cleansing procedures and the Minimum Recommended Concentration.

Mechanism of action

It has not yet been defined with certainty. However, activity seems to be linked to the strong oxidant power both at the level of the micro-organism's cell membrane (interrupting chemiosmotic function) and inside the microbial cell (irreversibly damaging essential enzymatic systems).

Peracetic acid is also oxidizing and tends therefore to clean and dislodge any material deposits.

Spectrum of action

Peracetic acid is characterized by rapid disinfectant action. In the laboratory, the solution at 0.35% was seen to be effective in 10 minutes at ambient temperature (20°C) on the following micro-organisms:

- bacteria in vegetative form, among which *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Enterococcus*, *Escherichia coli*;
- viruses such as HCV, HIV, HBV, *Corona virus*;
- yeasts, dermatophytes and moulds (*Candida albicans*, *Aspergillus niger*);
- mycobacteria such as *Mycobacterium tuberculosis*, *M. avium*, *M. terrae*, *M. smegmatis*;
- spores of *Clostridium sporogenes*, *Bacillus subtilis*, *Bacillus cereus*.

Compatibility with materials

The activated solution demonstrated *good compatibility* with materials used in the manufacture of medical devices, in particular endoscopes and automatic disinfectors. It can however cause coloration of the encasings.

Toxicity/precautions

Concentrated solutions (> 0.35%) and peracetic acid vapours coming into contact with the skin and mucous membranes cause irritation and are sometimes even caustic. For this reason, it is necessary to thoroughly rinse the medical devices treated and *wear protective personal equipment during the various phases of use:*

- Mask for acid vapours in cases of emergency;
- Protective gloves (neoprene or heavy rubber);
- Goggles;
- Complete protective clothing.

Commercial solutions at 0.15% are not corrosive or irritating (only slightly for the eyes).

The literature reports a TLV/TVA** value of 10 ppm. In the case of exposure, the following *first aid measures* are valid:

- Contact with the eyes: wash thoroughly with water for at least 10 minutes. Remove contact lenses if it is possible to do so easily. Visit an eye specialist;
- Contact with the skin: remove contaminated garments and wash affected skin areas with soap and water. Consult a doctor if irritation persists;
- Ingestion: the product, if ingested, can cause ulceration and inflammation of the upper digestive tract; it is preferable, therefore, not to induce vomiting but to use a safe gastric lavage;
- Inhalation: transfer the subject into a ventilated area. It may be necessary to use artificial respiration.

Disposal

Peracetic acid is not harmful or polluting to the environment since it degrades immediately into acetic acid, water and oxygen.

Indications for use

The *automated system* that uses cartridges of peracetic acid at 35% obtains in controlled conditions a solution *at 0.2%* and acts at about 55°C for a contact time of 12 minutes.

It does not seem to be a system particularly suited for the frequent decontamination of flexible endoscopes due to the cost of each cycle.

The stabilized and buffered solution at 0.35% has, according to the studies, the same indications becoming active in 5 minutes with respect to bacteria, fungi, viruses and mycobacteria and in 10 minutes with respect to spores. It must be prepared extemporaneously and is stable 24 hours. It can be used for 20 cycles and in any case up to a concentration not less than 2,500 ppm.

It contains corrosion inhibitors but is not recommended for use in washer-disinfector-endoscope machines that have components in aluminium or copper. Some tests showed variations in the appearance of the chrome of rigid endoscopes containing these metals.

The stabilized solution at 0.15% reports action times in the technical sheet of 10-15 minutes for high-level disinfection at 30 minutes for sporicidal action. This solution also must be activated and replaced every 24 hours.

As was observed also by the survey conducted at Otorhinolaryngology (ENT) Departments, there are various types of products marketed under the name of peracetic acid. The methods of use and contact times vary depending on the type of product and for this reason it is essential to pay close attention to the conditions of use provided by the manufacturer, in addition to verifying the compatibility of the product with the instruments to be disinfected.

** Threshold Limit Value-Time Weighted Average: average concentration of a chemical agent weighted on a work exposure of one workday of 8 hours and for 40 hours of work per week, to which operators can be exposed without manifesting adverse health symptoms.

Chlorine Dioxide (for example ClO₂ Tristel)^{10 11}

Active ingredient

It is a molecule composed of one atom of chlorine and two of oxygen (ClO₂). The biocidal potency of ClO₂ has been long recognized for use in various industrial applications and in the disinfection of drinking water. A particular characteristic of this disinfectant is *the capacity to disinfect a broad spectrum, in rapid manner and at low levels of concentration* thanks to its great oxidation capacity, more than 2.5 times that of chlorine.

It is used for manual systems, manual systems electronically controlled by a microprocessor and automatic systems.

Characteristics

ClO₂, being an unstable gas, cannot be transported and thus *must be generated at the moment of use*. The patented method by "Tristel" provides for generation through the mixing of a solution of sodium chlorite and a mixture of organic acids, predominately citric acid. The reaction of the two precursors, almost instantaneous, produces chlorous acid that dissociates to release the ClO₂ gas in an aqueous solution for immediate use at a suitable concentration for the sporicidal disinfection of the semi-critical medical device. The ClO₂ concentration in the Wipes (detected through spectrophotometry immediately after the activation time) is 175-225 ppm (0.0175-0.0225%) while in the liquid form for immersion it is 50-60 ppm (0.005-0.006%).

Mechanism of action

ClO₂ reacts in an instantaneous manner with the surface of all types of micro-organisms, removing from them one electron and creating a breach, from which the vital constituents of the micro-organism escape with subsequent destruction due to the lytic effect. The means of destruction of the micro-organism prevents bacteria, fungi and viruses from developing a resistance, since it renders the creation of mutant varieties impossible.

Spectrum of action

ClO₂ activity, in its various formulations, has been tested in the laboratory by means of microbiological tests that have demonstrated its efficacy.

In particular, it *acts in 30 seconds in the wipes formulation and in 5 minutes in the liquid formulation by immersion* on the following micro-organisms:

- spores (tested on *Bacillus subtilis* and *Clostridium difficile*);
- mycobacteria (tested on *M. tuberculosis*, *M. avium* and *M. terrae*);
- viruses (tested on HBV, HCV, HIV, Polio virus, Adeno virus, Orthopox virus);
- fungi (tested on *Candida albicans*, *Aspergillus niger*);
- bacteria (tested on *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Enterococcus*).

Compatibility with materials

The integrity of the device treated with ClO₂, in single-use form, if used according to the instructions, is guaranteed: *no damage has ever been detected either in extensive laboratory tests or by experience over five years on the sample of wipes*.

Toxicity/Precautions

Personal safety during use of ClO₂ is confirmed by toxicological studies conducted on both animals and humans. Results demonstrate that at the concentrations used, *no reactions or contraindications exist*. The use of gloves is recommended in any case.

Disposal

ClO₂ solution *decomposes into a simple saline solution* and therefore does not have a negative impact on the environment and does not entail additional disposal costs.

Indications of use

ClO₂ is indicated for the high-level disinfection of endoscopes and semi-critical medical devices. The formulation of the solution present in the wipe is ready for use, with a contact time of 30 seconds, whereas the liquid formulation has a contact time of 5 minutes. The dilution is only with water at ambient temperature. No technical solutions are necessary concerning pH.

Glucoprotamin (for example, Sekusept Plus, Sekumatic)^{10 11}

Active ingredient

Glucoprotamin is a substance with a broad spectrum of activity obtained from the reaction between L-glutamic acid and coco-alkyl-1,3-propylene diamine. Both precursors are natural compounds and thus highly biodegradable.

Characteristics

A clear, aqueous solution, yellow in colour, non-volatile, that must be diluted in water from 1% to 4% without need of additional activators. It is usable both for manual use and for automatic systems.

The validity of the solution is 14 days.

Mechanism of action

Glucoprotamin acts by disorganizing the cell membrane, inhibiting the activity of the principal enzymes and denaturing cell proteins.

Spectrum of action

In particular, it acts on the following micro organisms:

- bacteria (tested on *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *simulans*, *Micrococcus luteus*, *Enterococcus hirae*, *Gemella morbillorum*, *Corynebacterium sp.*);
- mycobacteria (tested on *M. tuberculosis*, *avium* and *terrae*);
- viruses (tested on HIV, HVV, HCV);
- fungi (tested on *Candida albicans*).

The minimum contact time for the activity is 5 minutes for bacteria and 15 minutes for yeasts.

Compatibility with materials

The product was tested and approved for use on Olympus and Storz endoscopes, on Rusch anaesthesia equipment and on Martin Instruments.

Toxicity/Precautions

Health risks: eye irritation.

The literature reports a TLV*** value of 500 ppm.

Protection of respiratory passages: none, in normal conditions of use.

Protection of hands: wear protective goggles.

Protection of skin: none, in normal conditions of use.

In the case of exposure, the following *first aid measures* are valid:

- Contact with the eyes: wash thoroughly with water for at least 10 minutes. Remove contact lenses if it is possible to do so easily. Visit an eye specialist;
- Contact with the skin: remove contaminated garments and wash affected skin areas with soap and water. Consult a doctor if irritation persists;
- Ingestion: the product, if ingested, can cause ulceration and inflammation of the upper digestive tract; it is preferable, therefore, not to induce vomiting but to use a safe gastric lavage;
- Inhalation: transfer the subject into a ventilated area. It may be necessary to use artificial respiration.

Disposal

Discarding the product in waterways causes negative effects on micro flora, micro fauna and water organisms for a short period of time.

According to Italian legislation, disposal of used solutions is allowed with sinks, considering the strong diluting effect at work of the water used daily for hospitalised patients, given that sinks are employed in well-ventilated areas and water is being constantly run to accelerate outflow.

Indications for use

Glucoprotamin is indicated for the high-level disinfection and simultaneous cleansing of flexible endoscopes, anaesthesia equipment and semi-critical medical devices.

Glucoprotamin was taken into consideration since its use was found in several departments in the survey conducted at Hospital ENT Departments. Studies currently available in the literature evaluating antimicrobial efficacy evidence a wider spectrum of activity with respect to intermediate-level disinfectants, but *its efficacy on spores, a fundamental requirement for a high-level disinfectant is not documented. Further assessments are needed to confirm its use in the reprocessing of endoscopes.*

Conclusions

Disinfection occurs with a great variety of solutions. It is essential to emphasize that even if products marketed are composed of the same molecule, the formulations can be different and subsequently the use can be different as well.

Therefore, there is no such thing as the ideal disinfectant. Each of the solutions examined can ensure optimal disinfection if the method is observed, namely:

- Appropriate pre-disinfection cleaning and drying: the greater the microbial load left on the instrument, the more difficult it is to obtain a good result;

- The choice of the disinfectant most appropriate for the specific type of work (assess carefully the number of exams to be performed, the supply of instruments and personnel as well as the training of said personnel);
- In the case of a multipurpose disinfectant, a periodic check of the MEC is to be performed;
- Compliance with contact times (not only to optimise disinfection but also to avoid damage to instruments);
- Reprocessing all parts of the endoscope;
- Sufficient drying and storage of the instrument.

*** Threshold Limit Value-Time Weighted Average: average concentration of a chemical agent weighted on a work exposure of one workday of 8 hours and for 40 hours of work per week, to which operators can be exposed without manifesting adverse health symptoms.

Bibliography

- 1 ECRI. Healthcare Product Comparison System. *Duodenoscopes; Gastrosopes. Choledoscopes* Plymouth 2004, pp. 1-10.
- 2 Society of Gastroenterology Nurses and Associates. *Guidelines for the use of high-level disinfectants and sterilants for reprocessing of flexible gastrointestinal endoscopes.* Gastroenterol Nurs 2004; 27:198-206.
- 3 Agolini G, Raitano A, Vitali M. *Glutaraldeide, una saga tutta italiana.* View & Review Hospitals 1999;5:7-15.
- 4 Scott E, Gorman S. *Glutaraldehyde.* In: Block SS, ed. *Disinfection, sterilization and preservation.* Philadelphia: Lippincott Williams & Wilkins; 2001.
- 5 McDonnel G, Pretzer D. *New and developing chemical antimicrobials.* In: Rutala WA, Weber DJ. and the Healthcare Infection Control Practices Advisory Committee, ed. *Draft guideline for disinfection and sterilization in healthcare facilities.* CDC University of North Carolina, Chapel Hill; 2002.
- 6 Rutala WA, Weber DJ. *New Disinfection and Sterilization Methods.* Emerging Infectious Diseases 2001;7:348-53.
- 7 Rutala WA, Weber DJ. *Disinfection of endoscopes: review of new chemical sterilants used for high level disinfection.* Infect Control Hosp Epidemiol 1999;20:69-76.
- 8 Curti C. *Una gestione razionale dei principi attivi usati per la disinfezione/sterilizzazione ospedaliera; schede monografiche: Acido peracetico.* In: Raitano A, Curti C, Agolini G, eds. *Igiene e disinfezione clinica nelle strutture ospedaliere. Principi e tecniche applicate per gli anni 2000.* Milano: Edizioni Kappadue 2002.
- 9 Malchesky PS. *Medical application of Peracetic Acid.* In Block SS, ed. *Disinfection, sterilization and preservation.* Philadelphia: Lippincott Williams & Wilkins;2001.
- 10 Awad Z, Pothier DD. *A potential ranger of flexible endoscopy sheaths: a deattached tip and how to retrieve it.* J Laryngol and Otol 2009;123:243-4.
- 11 Society of Gastroenterology Nurses and Associates. *Guidelines for the use of high-level disinfectants and sterilants for reprocessing of flexible gastrointestinal endoscopes.* Gastroenterol Nurs 2004;27:198-206.