
Contemporary Review

Guidelines for Reprocessing Nonlumened Heat-Sensitive Ear/Nose/Throat Endoscopes

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Endoscopes have become an indispensable instrument in the daily activity of the ear/nose/throat (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, whereas to date specific references to ENT endoscopes do not exist. The diagnostic ENT endoscope does not generally have an operative channel; it is shorter and thinner and has a much more frequent usage, also in the outpatient 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 article proposes: 1) to standardize the correct way to carry out the disinfection procedure of heat-sensitive nonlumened ENT endoscopes to reduce to a minimum the possibility of errors or oversights; and 2) to guarantee the disinfection within a limited time frame, appropriate for an ENT outpatient department. In the initial phase, the critical areas encountered in ENT endoscopy are determined. This is followed by an examination of the literature to identify existing guidelines for the reprocessing of endoscopes (mainly digestive and respiratory), with a view to establishing a common disinfection procedure for nonlumened ENT endoscopes. Finally, the new methods of disinfection developed specifically for the reprocessing of ENT endoscopes are examined and discussed.

Key Words: Heat-sensitive ENT endoscopes, cleaning, disinfection.

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INTRODUCTION

Endoscopes have by now become an irreplaceable instrument in the daily activity of otorhinolaryngologists, 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 medical devices.

Many studies^{2–4} agree that in nearly all of the infections transmitted to the patient after an endoscopic examination, a defect in the cleaning and disinfection procedure was shown to exist. This can occur in particular during the prewashing step (12%), the washing/disinfection step (exposure time, inappropriate disinfectant; 73%), and drying and storage (12%).

Flexible endoscopes are heat sensitive and therefore cannot be sterilized in an autoclave but must be disinfected.⁵

In recent years, scientific knowledge has become consolidated regarding 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.

Ear/nose/throat (ENT) diagnostic endoscopes, although conceptually similar to gastroscopes or bronchoscopes, differ in the absence of the operating channel, their smaller size and construction, and their more frequent use, including in outpatient situations. As a result, the guidelines used in digestive and respiratory endoscopy are not always functional in ENT departments, because they do not anticipate the dynamism and intensity of the work carried out there.

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OBJECTIVES

This document, which specifically concerns heat-sensitive nonchanneled ENT endoscopes, proposes to:

- Standardize the correct method of execution with regard to disinfection procedures for heat-sensitive nonchanneled ENT endoscopes.
- Prevent the transmission of infections.
- Increase operator safety.
- Guarantee disinfection under tight deadlines in time frames suitable for an ENT outpatient facility.
- 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 nonchanneled 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 sources of infection are therefore represented by infected or colonized patients,⁶ The environment is also a major source of infection,⁷ 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 (0.2 μm) can help to eliminate or considerably reduce the quantity of bacteria transmitted by drinking water.

An observational study⁸ conducted at 26 hospitals in the United States revealed that the majority of endoscopes and bronchoscopes were being improperly disinfected 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: ENT endoscopes (entering into contact with mucous membranes or damaged skin) are considered semicritical medical devices for which the risk of infection is intermediate and for which high-level disinfection is required.⁹⁻¹¹

High-level disinfection presumes the inactivation of all vegetative forms of bacteria, mycobacteria, fungi, and viruses, but not necessarily of all bacterial 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 microorganisms or other potentially dangerous chemical substances for both the doctor and the patient.

HIGH-LEVEL DISINFECTION OF ENDOSCOPES: TRADITIONAL AND EMERGING METHODS

We have categorized disinfection systems into two types^{10,12-21}:

Traditional—systems acquired principally from digestive and respiratory endoscopy, including:

- *Immersion*. In these systems, the operator manually performs all the steps involved in disinfection.
- *Automatic*. In these systems, disinfection and if applicable prewashing 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 prewashing, rinsing, and drying) and part occurs automatically (disinfection with time calculations, disposal of the disinfectant).
- *Sterile protective sheaths*. These constitute a protective barrier of the endoscope from contaminations and not a system of disinfection.

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:

- 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.
- The entire endoscope must be cleaned and disinfected. To be avoided are the wall-fitted tubes, in which only the insertion tube of the instrument is placed, preventing contact between the control head and the disinfectant. As a consequence, this latter part of the instrument remains potentially contaminated.

After analyzing the reference literature, the authors make the following recommendations divided according to the type of disinfection system (Table II).

Following, we detail the main considerations and evaluations for each system presented.

TABLE I.
Endoscope Disinfection Treatment: Steps and Goals.

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

Traditional Systems

Manual disinfection system by immersion. 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.

Automatic disinfection systems. These are automated systems that disinfect or sterilize the endoscope. Until recently, only washer disinfector endoscopes designed for gastroscopy and bronchoscopy were available on the market; today, several firms have made available automatic washer endoscopes created specifically for nonchanneled 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. 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.

To reduce the possibility of contaminations, the washer disinfector endoscopes must be in turn regularly disinfected or sterilized. The majority are furnished with thermal autodisinfection 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 (prewashing, 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 autodisinfection/autosterilization.
- The presence of visual and sound alarms.
- Required space.
- Registration of procedures performed, an aspect strongly advised today because of lawsuits. In general, the data recorded and/or printed are:
 - Identification of the instrument that is undergoing reprocessing.

TABLE II.
Endoscope Disinfection Treatment: Steps Comparison.

	Manual Disinfection System by Immersion	Automatic Disinfection System	Manual Disinfection System With Wipes With ClO ₂	Immersion Disinfection System With ClO ₂ Electronically Controlled by a Microprocessor
Step 1. Disconnection and inspection	<p>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 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.</p> <p>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 time frame limits the cost of repair, which rapidly increases if the instrument continues to be used.</p>			
Step 2. Cleaning	<p>The purpose is to remove residues of organic and inorganic substances along with micro-organisms. 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.</p> <p>An enzymatic cleaning solution is necessary that must be changed after every use, because it does not have any biocidal activity and thus allows germs to survive in it.</p>	<p>Some washer disinfectors perform this step automatically.</p>	<p>Cleaning is performed with the cleansing wipe, a nonwoven 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-directional manual scrubbing action going from its proximal end to its distal end to physically remove all dirt and visible material. The operating handle of the instrument should be cleaned before the insertion tube. The action is facilitated by the solution contained in the wipe. Average performance time is 30–60 seconds.</p> <p>The wipes are for single use, are to be opened immediately before use, and must be disposed of in hospital clinical waste receptacles after use.</p>	<p>Same as for manual disinfection system by immersion.</p>

(Continued)

TABLE II.
(Continued).

	Manual Disinfection System by Immersion	Automatic Disinfection System	Manual Disinfection System With Wipes With ClO ₂	Immersion Disinfection System With ClO ₂ Electronically Controlled by a Microprocessor
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.	Some washer disinfectors automatically perform this step automatically.	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.	Same as for manual disinfection system by immersion.
Step 4. Disinfection	<p>Test the disinfectant used, if a multipurpose one, at the start of each day to assess the 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.</p> <p>The use of a multipurpose disinfectant does not permit tracking the procedure to check that decontamination was correctly performed.</p> <p>Completely immerse the instrument in the disinfectant solution.</p> <p>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.</p>	<p>Use only those disinfectants specifically indicated by the machine manufacturer of the washer disinfectant endoscope as compatible with endoscopic instruments.</p> <p>Position the endoscopic instruments in the appropriate basket according to the directions stated in the user's manual and make sure they are not touching each other.</p> <p>Close the lid on the basin and start the selected cycle.</p> <p>If the machine is equipped to handle it, always proceed to the drying cycle.</p> <p>A weekly disinfection cycle is advisable after prolonged periods of disuse and after any technical assistance.</p>	<p>Disinfection is performed with the sporidical disinfectant wipe. The wipe is a nonwoven cloth soaked in an organic acid-based solution (prevalently citric acid with minute quantities of boric and sorbic acids), to which are applied two doses of special sodium chlorite-based activation foam (NaClO₂).</p> <p>After scrunching the wipe for 15 seconds, chlorine dioxide is generated. The activated solution is a neutral pH, which ensures maximum safety both for the skin and for the device.</p> <p>The wipe is laid across the palm of the hand and rubbed along the device using a one-directional 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 seconds.</p> <p>The wipes are for single use, are to be opened immediately before use, and are to be used immediately after activation.</p>	<p>After cleaning, the instrument is situated in the compartment of the base unit to which the disinfectant is added.</p> <p>The ClO₂-based disinfectant is packed in sachets with two compartments that are separated by a thin membrane and that contain the two precursor solutions: 50 mL of sodium chlorite solution and 50 mL of organic acid solution.</p> <p>Manipulating the sachet breaks the membrane and allows the two solutions to mix together. After about 30 seconds, a concentrated single-use solution of ClO₂ is generated. The solution is diluted in 5 L of cold water and then poured into the base unit holding the previously cleaned instrument.</p> <p>A sensor automatically begins the contact time (5 minutes) when the compartment of the base unit is full of 5 L of disinfectant. If the level of disinfectant is not adequate, the cycle is not validated.</p> <p>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.</p> <p>At the end of the disinfection cycle, the disinfectant is automatically emptied out directly into the sink.</p>

(Continued)

TABLE II.
(Continued).

	Manual Disinfection System by Immersion	Automatic Disinfection System	Manual Disinfection System With Wipes With ClO ₂	Immersion Disinfection System With ClO ₂ Electronically Controlled by a Microprocessor
Step 5. Final rinse	<p>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.</p>	<p>Some washer disinfectors endoscopes perform this step automatically.</p>	<p>Rinsing is performed with the rinsing wipe, a nonwoven cloth soaked in a deionized 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 is for single use, is to be opened immediately before use, and must be subsequently disposed of in hospital clinical waste receptacles.</p>	<p>Same as for manual disinfection system by immersion in the unit. The valve remains open, and the rinse water is discharged directly into the sink.</p>

(Continued)

TABLE II.
(Continued).

	Manual Disinfection System by Immersion	Automatic Disinfection System	Manual Disinfection System With Wipes With ClO ₂	Immersion Disinfection System With ClO ₂ Electronically Controlled by a Microprocessor
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.	Some washer disinfectors perform this step automatically.	Unnecessary.	Same as for manual disinfection system by immersion.
Step 7. Storage	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 examination and 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.</p>			
Reprocessing time	10–30 minutes	12–30 minutes	2–3 minutes	7–12 minutes
Reprocessing costs	€5–15	€4–10	€6–7	€4–6

MEC = minimum effective concentration.

- 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, because 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 use, which are 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 to guarantee the same level of activity compared to manual disinfection systems, about 20 additional endoscopes would have to be acquired.

Emerging Systems

Manual disinfection system with wipes. The disinfection system by means of wipes is a comprehensive manual sporicidal disinfection treatment of semicritical, nonchanneled, and heat-sensitive medical devices. Treatment time is only 2 to 3 minutes.

The active ingredient used in this high-level disinfection process is chlorine dioxide (ClO₂), 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 wiping action increases the efficacy of the cleaning and disinfection steps.



Fig. 1. Washer disinfector endoscope dedicated to otorhinolaryngology.

The wipes are for single use and thus permit tracking of the decontamination procedure to monitor its correct execution.

The use of wipes with ClO₂ leads to a notable reduction in disinfection times compared with other disinfectants of equal efficacy used in immersion methods. The Tristel wipe system in fact was designed for the needs of the ENT department, ensuring the disinfection at the sporicidal level in time frames that permit a rapid turnaround of the instrument.

In addition, they are safe from a health standpoint, because the wipes are nontoxic, nonirritating, and nonsensitizing.

The safe use of ClO₂ enables a manual wiping technique not possible with the other traditional high-level disinfectants.

Each wipe procedure is single use, which allows an audit trail to be implemented, because 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.

Immersion disinfection system electronically controlled by a microprocessor. Recently put on the market, this is a high-level disinfection system of semicritical 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



Fig. 2. Immersion disinfection system electronically controlled by a microprocessor.

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. 2) 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. Studies demonstrate that the level of ClO_2 present in the disinfectant solution is a valid substitute for glutaraldehyde.^{23,24}

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 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. All the recorded data can be downloaded onto a computer 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 trolley in a manner that makes it easily transportable. 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 to empty out the used disinfectant.

The immersion system with electronic control represents an important evolutionary step compared with the traditional manual immersion system using a tray because, although it does not 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. Although investment and management costs are less in comparison with the automatic system, the qualitative level of disinfection is perfectly adequate.

Sterile protective sheaths. This is an endoscope encasing system that can represent an alternative to the high-level disinfection of endoscopes (Fig. 3).

It must, however, be emphasized that various studies^{25,26} have demonstrated the necessity to clean the entire endoscope (including the control head) with an enzymatic cleanser, followed by a medium-level disinfectant with 70% ethanol immediately after the removal of the sheath and before fitting the next one, to guarantee the equivalent of a high-level disinfection. Small viruses are

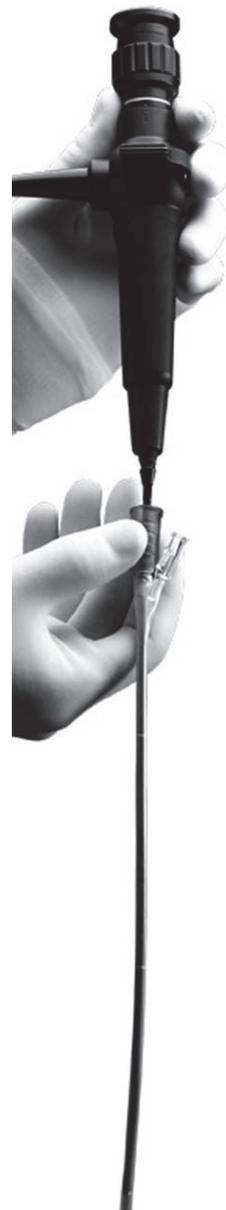


Fig. 3. Sterile protective encasing.

capable of penetrating the sheath and remaining on the surface of the instrument.

From our investigation conducted in 2010 at ENT departments in Italy in 2010 using multiple choice questionnaires, it was ascertained that the practice of cleaning and disinfecting is done in only 2% of cases after removal of the sheath.

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

- There is an increase in the diameter of the endoscope, with the subsequent greater likelihood of discomfort for the patient.
- The control head is unprotected against contamination.
- There is a possibility of breakage of the sheath during the examination (cases have been reported of the tip of the sheath detaching and getting stuck in the patient's airway).²⁷
- There is a possibility of damage to the endoscope when removing the sheath.
- Vision is not optimal.
- Costs: endoscopes of various brands moreover require specific sheaths and their cost ranges from 8 to 25 euros.

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, because infections are rarely detected and linked to the execution of the endoscopic examination performed.

For these reasons, the scientific community questions whether it is appropriate to carry out routine culture tests on endoscope surfaces. Moreover, the culture methods currently in use to monitor outcomes have not been rigorously validated, resulting in the danger of underestimating results (false negatives) or overestimating results (false positives), and consequently causing potential harm to patients and health facilities.²⁸

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

The Association for Professionals in Infection Control and Epidemiology and the Centers for Disease Control and Prevention do not recommend routinely conducting microbiological tests and advise them only in cases of epidemics. We are in agreement with this decision.

TRACKING SYSTEMS

In every unit where endoscopic examinations are performed, it may be appropriate to introduce a registration system of all procedures carried out.⁵ In the case of

introducing such a system, the following information would need to be recorded for each procedure:

- Sequence number.
- Patient's first and last name and date of birth.
- Description of procedure and time 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 should maintain:

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

CONCLUSIONS

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 have shown 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 (e.g., human and economic resources, available space, volume of activity, number of endoscopes).

The choice of the disinfection system is made in consultation with the director of the unit, the pharmacy service, and the committee assigned the task of infection control of the local health unit.

The nursing staff as well as the doctor using the endoscope are responsible for the endoscope disinfection process.

Disinfection must be carried out by adequately trained staff with periodic checks of their skill levels and competence.

BIBLIOGRAPHY

1. American Society for Gastrointestinal Endoscopy. Technology Assessment Committee Position Paper. Transmission of infection by gastrointestinal endoscopy. *Gastrointest Endosc* 1993;885–888.
2. Birnie GC, Quigley A, Clements GB, et al. Endoscopic transmission of hepatitis B virus. *Gut* 1983;24:171–174.
3. Bronowicki JP, Venard V, Botte C. Patient-to-patient transmission of hepatitis C virus during colonoscopy. *N Engl J Med* 1997;337:237–240.
4. Morris J, Duckworth GJ, Ridgway GL. Gastrointestinal endoscopy decontamination failure and the risk of transmission of blood-borne viruses: a review. *J Hosp Infect* 2006;63:1–13.
5. Reprocessing degli endoscopi. *Indicazioni operative*. Bologna, Italy: Agenzia Sanitaria Regionale dell'Emilia-Romagna; 2006.
6. Sud-Ouest-Centre de coordination de lutte contre les infections nosocomiales. *Prévention du risque infectieux en imagerie médicale non interventionnelle*. Bordeaux, France: Coordination Centre for the Fight Against Nosocomial Infections; 2004.
7. Culver DA, Gordon SM, Mehta AC. Infection control in the bronchoscopy suite. *Am J Respir Crit Care Med* 2003;167:1050–1056.
8. Rutala WA, Weber DJ. Reprocessing endoscopes: United States perspective. *J Hosp Infect* 2004;56(suppl 2):27–39.
9. Spaulding EH. Chemical disinfection of material and surgical materials. In: Block SS, ed. *Disinfection, Sterilization and Preservation*. Philadelphia, PA: Lea & Febiger; 1968:617–641.
10. Centers for Disease Control and Prevention. *Guideline for Disinfection and Sterilization in Healthcare Facilities*. Chapel Hill, NC: University of North Carolina; 2008.
11. Centers for Disease Control and Prevention. *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. Chapel Hill, NC: University of North Carolina; 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;28:138–155.
13. Alvarado CJ, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. *Am J Infect Control* 2000;28:138–155.
14. *Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting*. Canberra, Australia: Department of Health and Ageing; 2004.
15. *Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy*. London, UK: British Society of Gastroenterology; 2003.
16. *Gastrointestinal Endoscopy Equipment Evaluation and Procurement. A Guide to the Process*. London, UK: British Society of Gastroenterology; 2005:54–55.
17. Darbord JC. Importance of cleaning for reprocessing endoscopes and thermolabile sterile medical devices: French use and regulations. *J Hosp Infect* 2004;56(suppl 2):S40–S43.
18. Rey JF, Kruse A, Neumann C; ESGE (European Society of Gastrointestinal Endoscopy); ESGENA (European Society of Gastrointestinal Endoscopy Nurses and Associates). ESGE/ESGENA technical note on cleaning and disinfection. *Endoscopy* 2003;35:869–877.
19. Lim M, Gupta D. Flexible naso-endoscopic decontamination—rationalizing the next step forward. *J Hosp Infect* 2006;62:136–140.
20. Nelson DB, Jarvis WR, Rutala WA, et al. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Dis Colon Rectum* 2004;47:413–420.
21. Beilenhoff U, Neumann CS, Biering H, Blum R, Schmidt V, Rey JF; ESGE; ESGENA. ESGE/ESGENA guideline for process validation and routine testing for reprocessing endoscopes in washer-disinfectors, according to the 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* (in press).
23. Isomoto H, Urata M, Kawazoe K, et al. Endoscope disinfection using chlorine dioxide in an automated washer-disinfector. *J Hosp Infect* 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 Hosp Infect* 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 nasopharyngoscopes. *Am J Infect Control* 2009;37:408–413.
26. Baker KH, Chaput MP, Clavet CR, et al. Evaluation of endoscope sheaths as viral barriers. *Laryngoscope* 1999;109:636–639.
27. Awad Z, Pothier DD. A potential danger of flexible endoscopy sheaths: a detached tip and how to retrieve it. *J Laryngol Otol* 2009;123:243–244.
28. Beilenhoff U, Neumann CS, Rey JF, et al. ESGE-ESGENA guideline for quality assurance in reprocessing: microbiological surveillance testing in endoscopy. *Endoscopy* 2007;39:175–181.