ESGE–ESGENA guideline: Cleaning and disinfection in gastrointestinal endoscopy
Update 2008

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1. Introduction

The appropriate reprocessing of flexible endoscopes and endoscopic accessories is an essential part of safety and quality assurance in gastrointestinal endoscopy. Since 1994, the ESGE–ESGENA Guideline Committee of the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) has developed a number of guidelines focused on hygiene and infection control in endoscopy. The present guideline updates and combines the following guidelines and technical notes:

- Guidelines on cleaning and disinfection in gastrointestinal endoscopy – update 1999 [1]
- ESGE/ESGENA Technical note on cleaning and disinfection (2003) [2].

The aims of this updated ESGE–ESGENA guideline are:

- To set standards for the reprocessing of endoscopes and endoscopic devices prior to each individual procedure, whether performed in hospitals, private clinics, or doctors' offices
- To support individual endoscopy departments in developing local standards and protocols for cleaning and disinfection in gastrointestinal endoscopy
- To support national societies and official bodies in developing national recommendations and quality assurance programs for hygiene and infection control in gastrointestinal endoscopy.

This guideline focuses only on flexible endoscopes and the accessories used in gastrointestinal endoscopy. It addresses a number of important aspects of safety in gastrointestinal endoscopy with special emphasis on avoiding infection that may result from inadequate reprocessing of endoscopes or endoscopic accessories. In addition to the general statements, it provides detailed technical protocols for the daily work of nurses and associates, as we are aware of multiple local variations in the use of general guidelines.

This ESGE–ESGENA guideline is a consensus prepared by endoscopists, microbiologists, hygienists, endoscopy nurses, and representatives of the biomedical industry.

In 2007 two guidelines were published that also address the necessity of cleaning and reprocessing standards in gastrointestinal endoscopy:

- the 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 [3]
- the ESGE–ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy [4].

These two guidelines must be taken into account in the process of establishing local quality management of hygiene and infection control in endoscopy. The ESGE–ESGENA guidelines are strong recommendations, but within each country, endoscopists, nurses, and hospital administrators have to comply with local regulations and national law, and at all times, it is important to follow manufacturers' instructions.

2. Definition of terms

Automated disinfection devices: Automated disinfection devices are intended to disinfect flexible endoscopes in a closed system after manual cleaning; thus their cycle includes disinfection and rinse steps only, and does not include cleaning.

Clean conditions: Conditions where surfaces have been cleaned satisfactorily and/or are known to contain minimal levels of organic and/or inorganic substances (EN 14885) [5].

Cleaning: Removal of blood, secretions, and any other contaminations and residues from endoscopes and accessories.

Clinical service provider: An organization, person, or persons legally responsible for the provision of a clinical service. This could be an institution (such as the health service), a hospital or department, or doctors working in their own premises.

Detergent: A compound, or a mixture of compounds, intended to assist cleaning. The term is often used to distinguish between soap and other chemical surfactants used for cleaning medical devices.

Disinfectants: Antimicrobial agents that are applied to nonliving objects to destroy microorganisms; the process is termed disinfection. Disinfectants should generally be distinguished from antibiotics (these destroy microorganisms within the body), and from antiseptics (these destroy microorganisms on living tissue).

Dirty conditions: Conditions where surfaces are known to or may contain organic and/or inorganic substances (EN 14885) [5].

Disinfection: Reduction of the number of viable microorganisms on a device by irreversible destruction, to a level appropriate for safe use on a patient, where sterilization of the device is not necessary. Disinfection is a prerequisite to sterilization. Disinfection should be carried out immediately after cleaning.

Endoscopes: Flexible endoscopes used in gastroenterology.

Endoscopic accessories: All devices used in conjunction with an endoscope to perform diagnosis and therapy, excluding peripheral equipment.

High level disinfectant: A germicide that inactivates all microbial pathogens, except large numbers of bacterial endospores, when used according to labelling [6]. The US Food and Drug Administration (FDA) further defines a high level disinfectant as a sterilant used under the same contact conditions except for a shorter contact time [7].

Pre-cleaning: Rinsing and flushing of scope channels at the examination site. The outer surfaces of the scope must be wiped off, preferably with a dedicated detergent solution.

Process chemicals: All chemicals used during the reprocessing procedures, including detergents, disinfectants, alcohol, etc.

Reusable accessories: Reusable accessories should be sterilized. Sterilization is carried out after cleaning, as detailed below. Manufacturers provide validated standard reprocessing parameters (e. g. temperature and time) for cleaning, disinfection, and sterilization.

Standard operating procedures (SOPs): Describe each step of the reprocessing process in detail including:

- What manual handling processes must be carried out in each individual step in the correct sequence
- Who should carry out these steps
- Which tools must be used
- Which process chemicals must be applied and under what conditions, e. g. of concentration, temperature, contact time.

Single-use accessories: Also called "disposable" accessories. These are provided sterile, ready for use. The opening of a sterile

a. Inadequate reprocessing of endoscopes and accessories
Inadequate cleaning (e. g. inadequate manual cleaning and brushing of endoscope channels)
Contaminated cleaning accessories (e. g. cleaning brushes)
Use of unsuitable or incompatible detergents and disinfectants
Inadequate concentrations, contact time of agents and temperature
Contaminated or time-expired solutions
Contaminated rinsing water
Fixed organic material in endoscopes or washer-disinfectors
Use of nonsterile accessories in invasive diagnosis and treatment (e. g. nonsterile biopsy forceps, polypectomy snares)
Inadequate reprocessing of water bottles (e. g. no sterilization)
Use of tap water in water bottles
b. Inadequate transport and storage of endoscopes
Insufficient drying before storage (e. g. *Pseudomonas* spp.)
Inappropriate storage conditions
c. Contaminated or defective washer-disinfector
Contaminated pipes, containers, etc.
Contaminated final rinsing water
Biofilms in water pipes, containers or washer-disinfectors
Mechanical/electronic defects of washer-disinfector
Incorrect use of washer-disinfector (e. g. wrong connections)
Wrong or inadequate load (i. e. bottles, flasks)
Lack of regular maintenance of washer-disinfector according to manufacturer's recommendations
Lack of self disinfection cycle run
d. Design limitations and damaged endoscopes
Small lumina, branched channels, not accessible to cleaning brushes
Damage to the surfaces (internal and external) of the endoscope, providing potential for contamination
e. Contaminated water in the endoscopy unit
Contaminated mains water pipes/supply
Contaminated or inadequate water supply systems (filtration etc.)
f. Contaminated ultrasonic cleaner
g. Insufficient drying and storage
h. Shortcuts due to insufficient number of endoscopes and/or reprocessing resources for the clinical workload

Table 1 Potential weaknesses and deficiencies in endoscope reprocessing (modified from references 10 and 11 [10, 11]).

package implies immediate use. After a single-use device has been employed, all materials should be appropriately disposed of. Under no circumstances should a single-use device be reprocessed.

Sterilization: Complete destruction of all microorganisms including bacterial spores. Also, a validated process used to render a device free from all forms of viable microorganisms (ISO 11137) [8].

User: Person or department using equipment; organization(s) or persons within those organization(s) who operate and/or use the equipment

Washer-disinfectors: According to the definition of EN ISO 15883, washer-disinfectors are intended to clean and disinfect medical devices, e. g. flexible endoscopes, within a closed system [9].

3. Endoscopy-related infections

Endoscopic procedures are well established in the diagnosis and therapy of gastrointestinal diseases. In addition to other procedure-related risks, the risk of infection due to endoscopic procedures has to be taken into consideration. Endoscopy-associated infection risks are categorized as follows:

- endogenous infection
- exogenous infections caused by inadequately reprocessed equipment. (endoscopes and accessories can be vehicles for pathogenic or facultative-pathogenic germs that are transmitted from previous patients)
- risks of infection to endoscopy staff.

Microorganisms may be spread by inadequately reprocessed equipment, from one patient to another, or from patients to staff members. There are a number of weaknesses and potential deficiencies in endoscope reprocessing which might be sources for microbial contamination and transmission of infectious material (**Table 1**).

Since the late 1970 s there have been sporadic reports of nosocomial infections linked to endoscopic procedures. Bacterial infections have been acquired during endoscopy, caused for example by *Salmonella* spp, *Helicobacter pylori* and *Pseudomona* spp [12 – 16]. Viruses such as hepatitis B and C have also been transmitted during endoscopy [17,18]. The majority of documented cases were caused by noncompliance with national and international reprocessing guidelines [12 – 18]. Nevertheless, studies have shown that endoscopic procedures do not increase the risk for transmitting hepatitis C virus [19]. Additionally, fungi can be transmitted via endoscopic procedures [20 – 22].

Patients with immune deficiency syndrome or severe neutropenia, those undergoing immunosuppressive chemotherapy, or those having artificial cardiac valves have an increased risk of infection, and therefore therapeutic procedures carry a higher risk of infection. Patients harbouring clinically latent infections (hepatitis, HIV, tuberculosis, salmonellosis, infections caused by *Helicobacter pylori*) may not be aware of their carrier status, and therefore, all patients should be considered potentially infective. Tuberculosis infection is becoming more common. The emergence of multi-drug-resistant strains of *Mycobacterium tuberculosis* and the high incidence of infections with *M. avium intracellulare* among HIV-infected patients has led to a greater awareness of the risk of transmission of mycobacteria during bronchoscopy. Mycobacteria in general and especially some waterborne

mycobacteria (such as *M. chelonae*) show resistance to glutaraldehyde [23].

Creutzfeldt–Jakob disease (CJD) and variant-CJD (vCJD) are so-called prion diseases. The infectious particles are extremely resistant to standard reprocessing procedures. The ESGE and ESGENA developed a guideline relating to vCJD and gastrointestinal endoscopy in 2001; this guideline is currently under review [24].

4. Principles of infection control

As the carrier status of patients is often unknown:

- All patients should be treated as potentially infectious.
- All endoscopes and accessories used in endoscopy should be reprocessed following every endoscopic procedure, using a uniform, standardized reprocessing protocol.

Patients undergoing digestive endoscopy should be examined and treated without risk of transmission of infection or side effects that may result from inadequate reprocessing of endoscopic equipment.

Regular quality control and the institution's adherence to validated reprocessing procedures is the responsibility of both endoscopists and clinical service providers and should be monitored by the hospital-based hygiene/cross-infection control department, or an external organization [3,4] as appropriate.

Traditionally patients with known infections are scheduled to the end of the daily patient list. However, given the universal endoscope reprocessing regime, which presumes that all patients are potentially infectious, there is not normally a need to examine patients with known infection at the end of the daily clinic. Nevertheless infection control policies should include this recommendation in order to make staff aware of infections, to minimize the potential risk of cross-infection, and to ensure a proper cleaning and disinfection of the working environment.

In order to correctly apply disinfection instructions, it is important to understand what is required before an infection actually takes place. All the links in the so-called "chain of infection" need to be intact before a pathogen can be transmitted. If only one link is broken, infection cannot occur.

The links of the chain of infection are:

- Viable microorganisms are present
- Sufficient number of pathogens needed to initiate infection
- Host is susceptible to the infection present
- Pathogen enters host through appropriate portal of entry (e.g., gastrointestinal agent into the gut, bloodborne agent into the bloodstream).

Infection control provides activities or precautions that may be used to attack these links and break the chain of infection:

- cleaning, disinfection, and sterilization of medical equipment
- correct use of personal protective equipment
- personal hygiene
- engineering controls (ventilation, building design, clean water supply)
- cleaning, disinfection of environmental surfaces
- adequate administrative control and support
- training and continuing education
- adequate written standardized operating procedures (SOPs)
- documentation.

6. Health and safety of endoscopy personnel

Contamination-related hazards come in two forms: from cross-infection from patients or equipment and from chemicals used in cleaning and disinfection. Microorganisms may also be transmitted directly from the patient to endoscopy personnel. Therefore protection from direct contact with contaminated endoscopes, accessories and patient fluids is essential. Protection against chemicals used for reprocessing is of the utmost importance to avoid toxic and allergic reactions.

All staff involved in the reprocessing procedure should wear appropriate protective clothing including:

- chemically resistant single-use gloves
- protective glasses and face masks
- protective full-face visors
- special examination gown or coat (long-sleeved, moisture-resistant) or plastic aprons with arms.

Changing from reusable to single-use devices additionally reduces risks to staff as the handling and reprocessing of contaminated equipment is then unnecessary.

A department-specific policy should be available that covers issues relating to spillages, chemicals, detergents, and body fluids, and the appropriate equipment to implement the policy should be available. Care must be taken in the handling of sharps, including spiked biopsy forceps and flexible needles, to avoid needlestick injury. Contaminated devices must be transported from the endoscopy room to the reprocessing room in closed containers, with attention paid to protective measures regarding staff and environment. It is emphasized that reprocessing must be started immediately after the procedure. Splashing should be avoided throughout the reprocessing procedure in order to prevent contact with infectious material and with disinfectants or detergents.

Staff known to be disease carriers should avoid duties that could transmit their disease to patients.

Health surveillance is recommended for all staff working with potentially sensitizing or allergy-inducing chemicals, e.g. related to allergic asthma, skin and/or mucosal sensitivity problems. It is recommended that all staff be offered appropriate vaccination against infectious agents, for example hepatitis B.

7. General requirements

7.1 Classification of endoscopic equipment

According to the Spaulding classification, most flexible endoscopes used in gastrointestinal endoscopy are classified as semi-critical devices, as they come into contact with mucous membranes [25,26]. Semi-critical devices require disinfection, but sterilization is not necessary. In the case of percutaneous procedures (e.g. laparoscopy, percutaneous cholangioscopy), endoscopes are classified as critical and therefore must be sterile.

Accessories which come into contact only with the skin and mucosa (e.g. mouthguards) do not need to be sterile, but must undergo high level disinfection. Mouthguards are often employed as single-use items due to the need for traceability.

Endoscopy accessories which penetrate the mucosal barrier (e.g. biopsy forceps, guide wires, polypectomy snares, injection needles, etc) are classified as critical devices and therefore must be sterile at the point of use [25,26].

Single-use devices should not be reprocessed. National regulations should be followed.

7.2. Aims of the reprocessing procedure

The purpose of the reprocessing procedure is to reduce all pathogens to such a level that they do not cause any harm to future patients or to personnel handling the equipment.

As all patients must be considered to be potential risks, each endoscope and device must be reprocessed to the same standards following every endoscopic procedure (universal precautions).

The reprocessing of flexible endoscopes must be of guaranteed effectiveness in at least the following respects:

- cleaning efficacy
- disinfecting efficacy
- bactericidal efficacy
- mycobactericidal and/or tuberculocidal efficacy
- fungicidal and/or yeasticidal efficacy
- virucidal efficacy against enveloped and non-enveloped viruses.

Although for reprocessing of semi-critical instruments sporicidal activity is not mandatory under used conditions (e.g. time, temperature), the EN ISO 15883-4 recommends the sporicidal activity of the disinfectant at extended time. The disinfectant should reduce the population of bacterial spores in the efficacy test by not less than 6 log10 within 5 hours' exposure at the minimum time, the minimum temperature and at the minimum concentration to be used in the washer-disinfectors (EN ISO 15883-4, paragraph 4.4.2.5) [27].

7.3. Staff requirements

To ensure appropriate and adequate reprocessing, the following personnel issues should be considered:

- Sufficient number of trained staff and sufficient time are prerequisites for correct reprocessing of endoscopes and accessories.
- Dedicated trained staff: only specially trained and competent personnel should carry out the reprocessing of endoscopic equipment, and this applies to both routine and emergency endoscopy.
- Regular practice and updated training are essential to maintain competency
- As the design of endoscopes varies according to type and manufacturer, it is essential that staff are familiar with the design and construction of all equipment in order to ensure safe and satisfactory cleaning and disinfection.

7.4. Reprocessing room

Reprocessing of endoscopic equipment should only be undertaken in a separate, purpose-designed reprocessing room, in order to:

- minimize the risks of infection and contamination for other personnel and the general public
- protect from chemicals used in cleaning and disinfection procedures (e.g. those associated with toxic/allergic reactions, hazardous vapors)
- protect from cross-contamination with potentially infectious material, blood, or body fluids.

It is the responsibility of the service provider to ensure that adequate facilities for reprocessing are available.

The reprocessing room must have separate dirty, clean, and storage areas. Contaminated and clean working areas must be strictly separated to avoid recontamination of reprocessed endoscopes and accessories.

The room should have appropriate ventilation and extraction in order to minimize the risks from chemical vapors. Separate sinks of adequate size for washing, disinfection, and rinsing of endoscopic equipment must be available. In addition a separate dedicated handwashing basin and hand-disinfection facility is required. The room should have the technical prerequisites for washer-disinfectors.

7.5. The reprocessing procedure

Reprocessing of flexible endoscopes generally includes the following steps, regardless of whether the procedure is manual or automated:

- *Pre-cleaning.* Immediately after use, macroscopically visible dirt is removed from external surfaces and the interior of scope channels.
- *Manual cleaning.* This consists of the manual leak test and the manual cleaning of external surfaces and the interior of scope channels, including brushing.
- *Rinsing.* This is removal of residual cleaning process chemicals that may interfere with the following disinfection stage.
- *Disinfection.* All microorganisms are reduced to such a level that they will not harm future patients.
- *Rinsing.* A further rinse removes the chemical load from the instruments/scopes which have been disinfected.
- *Drying.* Internal and external surfaces are dried to avoid growth of waterborne microorganisms
- *Storage.* Endoscopes are stored in a safe and closed cupboard which is also ventilated if this is appropriate.

The most important step in the reduction of microorganisms is the manual cleaning. It is impossible to disinfect or even sterilize an inadequately cleaned instrument. Protein debris can become fixed by chemicals on the channel surfaces of the scope if the cleaning and rinsing steps have not been carried out correctly. In short, all disinfection processes, whether done manually or by washer-disinfector, should be done only after appropriate manual cleaning.

The methods and requirements for testing the efficacy of the process and/or the activity of the disinfectant are based on the following standards.

- The required disinfection activity of the disinfectant is described in the European standard *EN 14885 Chemical disinfectants and antiseptics – Application of European standards for chemical disinfectants and antiseptics*.
- For automated processes in washer-disinfectors, phase 2 step 1 tests according to EN ISO 14885 and additional tests according to *EN ISO 15883 Washer-disinfectors*, parts 1, 4 and 5 are applicable [9, 27, 28].

Different reprocessing procedures are available (see **Fig. 1** and section 9):

- using washer-disinfectors
- using disinfection devices (automated disinfection devices)
- manual methods.

7.6. Manual versus automated reprocessing

ESGE and ESGENA strongly recommend the use of washer-disinfectors covering cleaning and disinfection, in order to:

- provide a standardized and validated reprocessing cycle in a closed environment
- document the process steps automatically (via a printer or electronically)
- provide highly reliable reprocessing
- minimize staff contact with chemicals and contaminated equipment
- minimize contamination of the environment

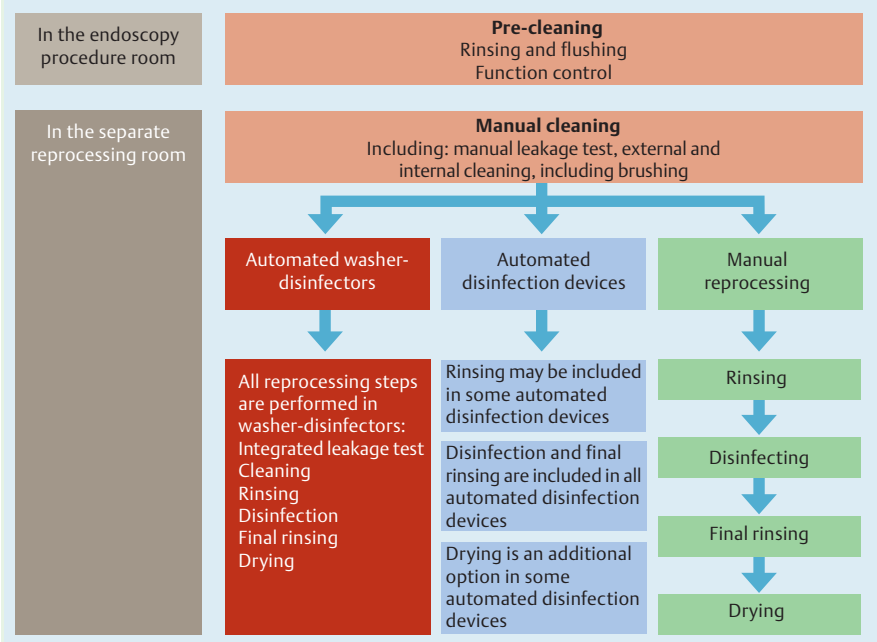

Fig. 1 Different methods for reprocessing endoscopes.

- facilitate the work involved for personnel
- lower the risk of damage of scopes.

However, if washer-disinfectors are not maintained and cleaned appropriately, they may themselves become an infection risk, from potential contamination of endoscopes during reprocessing.

Manual reprocessing also gives reliable results, if staff perform the reprocessing conscientiously, according to defined standard operating procedures. However, manual reprocessing cannot be validated, and moreover, staff may be exposed to chemicals and infectious material.

Even if washer-disinfectors are used in the endoscopy unit, staff should also be trained in manual methods to ensure safe reprocessing of equipment in the case of any machine failure. However, equipment for doing this without putting staff at risk must be available (e.g. adequate fume extraction facilities, appropriate personal protective equipment [PPE], etc).

8. Process chemicals

Chemicals used in endoscope reprocessing must be designed, tested and manufactured according to the European Medical Device Directive [29].

- Detergents are class I medical device products identifiable by the CE sign on the label.
- Disinfectants are class IIa medical device products identified by the CE sign plus a four-digit number on the label that identifies the responsible body.

Process chemicals should be compatible with endoscopes and washer-disinfectors/automated disinfection devices. Material compatibility tests are performed on test pieces or complete endoscopes using the detergent and the disinfectant alone and in combination. Manufacturers of endoscopes, chemicals and washer-disinfectors have to provide information about material compatibility (for example: depending on the internal standards of the endoscope manufacturer and the endoscope type, between 1000 and 2000 reprocessing cycles with the same endoscope have to be passed with no serious damage). Slight cosmetic changes are acceptable.

The ingredients of the detergent must be compatible with the disinfectant and not impair efficacy if small amounts of detergents are carried over. Rinsing between cleaning and disinfection must be used to reduce the concentration of residues (process chemicals and soiling including microbial contamination) to a level established as not exceeding that which would impair the efficacy of the chemical disinfectant (EN ISO 15883-4).

For that reason it is recommended a detergent and disinfectant from the same supplier should be used. Alternatively approvals from the suppliers of the detergent and disinfectant should be requested for combined use, with respect to compatibility of the material with endoscopes and to the mix of chemicals.

8.1. Detergents

Detergents can be divided in two main groups:

- with enzymatic and/or alkaline boosters
- with antimicrobial active substances.

Detergents containing antimicrobial active substances are mainly used for manual cleaning steps.

Most detergents from both groups contain low-foaming surfactants to lift off the soil (including particulate soil) and microorganisms from surfaces and keep them dissolved, emulsified, or dispersed in the cleaning solution. The low-foaming behavior of the surfactant for the pre-cleaning and the manual cleaning step at room temperature is necessary so that the device can be clearly visualized during the cleaning process, to avoid injury to personnel and to allow for complete cleaning of luminal surfaces.

For ultrasonic cleaning of endoscopic accessories it is recommended that the same detergent as used for the manual cleaning step should be employed. The cleaning solution should not be cloudy at elevated temperatures (up to 40 °C), to prevent injury to personnel. It is a challenge for detergent suppliers to provide a product that combines the features of low foaming at room temperature with a clear solution at higher temperatures. Currently only some detergents available on the market fulfill both criteria. Staff should be aware that some chemicals when heated

may exhibit increased vapor release, which could irritate the respiratory system.
Detergent solutions that are not claimed to have antimicrobial activity should be single use. Detergent solutions with claimed antimicrobial activity should be freshly prepared at least on a daily basis. In case of visible contamination the solution should be changed immediately. In the case of high frequency of reprocessing cycles, it is advisable to prepare fresh solutions at shorter intervals. Ideally, and whenever possible, detergent solutions should not be reused [23].

8.1.1. Detergents with enzymatic boosters

Detergents with enzymatic boosters contain one or more different types of enzymes, e.g. protease, amylase, or lipase. Enzymes are proteins with biological activity. Protease breaks protein debris into smaller subunits that are more soluble. Amylase catalyzes the breakdown of starch and lipase breaks up fat-containing debris. These types of detergent require a specific contact time as recommended by the manufacturer. When using enzymatic detergents for ultrasonic cleaning on endoscope accessories the container must be covered properly to avoiding an anaphylactic shock reaction caused by inhalation of enzyme-containing aerosols.

8.1.2. Detergents with alkaline boosters

Detergents with alkaline boosters contain chemical substances forming a mild alkaline cleaner. Alkaline substances lift off soil and help to dissolve it in the cleaning solution. Strong alkaline cleaners in the pH range >11 are not recommended for flexible endoscope cleaning, due to material incompatibility with some endoscope parts.

8.1.3 Detergents with enzymatic and alkaline boosters

Detergents with both types of booster combine the properties of enzymatic and alkaline detergents.

8.1.4. Detergents containing antimicrobial active substances

In some European countries detergents containing antimicrobial active substances are commonly used and recommended by the health authority, in the manual cleaning steps. Use of this type of product may reduce the infection risk to reprocessing personnel. The efficacy of these antimicrobial active detergents should be rated according European standard EN 14885. It is very important that the microbiological testing is done under dirty conditions. The minimal efficacy comprises bactericidal and yeasticidal activity and activity against enveloped viruses.
Detergents containing antimicrobial active substances can be used for up to one working day depending on national guidelines, manufacturer's instructions, and the amount of contamination. In general the Guideline Committee recommends that cleaning solutions are not reused. If detergents containing antimicrobial active substances are used, the cleaning solutions should be changed at shorter intervals and at least once a day.
In this type of detergent, commonly used active substances are amine compounds, peracetic acid and its salts, biguanidine, and quaternary ammonium compounds.
Tests of effective cleaning performance demonstrate that detergents containing amine compounds or salts of peracetic acid combine an alkaline booster effect with antimicrobial efficacy. Analogous combination effects are achieved by detergents containing enzymes and quaternary ammonium compounds.
The use of detergents with antimicrobial active substances does not replace the disinfection step.
Detergents containing aldehydes must not be used for the cleaning step, because they denature and coagulate protein (fixation).

8.2. Disinfectants

Disinfectants used at room temperature manually or in automated disinfection devices should be effective according to European standard EN 14885. Microbiological tests can be performed under clean conditions.
Disinfectants used for endoscope reprocessing must be fully effective at a designated temperature against a broad range of germs, such as bacteria, fungi, mycobacteria, and enveloped as well as non-enveloped viruses.
Active materials such as oxidizing substances and aldehydes, that interact chemically with the microorganism, show the required broad efficacy against germs. Examples from the aldehyde group include formaldehyde, glutaraldehyde, and orthophthalaldehyde and the oxidizing substances include hypochlorous acid, chlorine dioxide and peracetic acid and its salts.
Nonactive substances such as alcohols, phenols, and ammonium compounds are not recommended for endoscope disinfection as they do not show the required efficacy against germs.

8.2.1. Glutaraldehyde

Disinfectants based on glutaraldehyde are offered as concentrated or as ready-to-use (RTU) products applicable manually, for automated disinfection devices and in washer-disinfectors.
The RTU glutaraldehyde solutions range in concentration from 2.0% to 3.4% and have variable maximum use lives. The maximum use life of an alkaline (activated) 2% glutaraldehyde without surfactants is 14 days, 28 days for one product containing 3.4% active substance. Accurate monitoring of the glutaraldehyde concentration is required to ensure efficacy, which is not guaranteed at lower concentrations. The immersion time needed to cover the full range of germs is variable and needs to be determined according to EN 14885 or local standards.
The dilution ratio of concentrated glutaraldehyde-based disinfectants depends on the composition and the detected concentration–time relationship tested according to EN 14885 or local standards. Concentrated products based on glutaraldehyde are often used in combination with other aldehydes such as glyoxal and succinic aldehyde or other active substances such as quaternary ammonium compounds. Equivalent microbiological efficacy is achieved with a reduced concentration of glutaraldehyde in the application solution.
Glutaraldehyde has the advantages that it is effective, relatively inexpensive, and does not damage endoscopes, accessories, or processing equipment.
However, there are a number of disadvantages to glutaraldehyde, both for clinical staff and for patients. It has irritant and sensitizing properties. It can lead to allergic reactions (in skin, eyes, and ear, nose, and throat), and can cause dermatitis, conjunctivitis, nasal irritation, and occupational asthma [23,30]. Glutaraldehyde has been found to exhibit cytotoxicity [31] in cultured human cells. The hazards of glutaraldehyde use for staff are considerable, and toxicity has been suspected in 35% of endoscopic units [32] and detrimental effects established in up to 80% [33]. Use in a well-ventilated area and in closed containers with tight-fitting lids is recommended.

Advantages	Disadvantages
– In-use solution stable for 14 days (28 days for one product) (product-specific data) – Excellent compatibility with materials; does not damage	– Slow action against bacterial spores and mycobacteria at 25 °C – Sensitizing, irritant to skin, eyes and respiratory tract; stains skin; ventilation is recommended – Adverse effects for patients after insufficient rinsing of devices – Fixative, tends to create residue film; thorough cleaning is essential – Environmental health and safety measures are expensive

Table 2 Advantages and disadvantages of glutaraldehyde.

Advantages	Disadvantages
– In-use solution is stable for 7–14 days – Excellent compatibility with materials; does not damage	– Slow action against bacterial spores – Irritant to eyes and respiratory tract; stains skin; ventilation is recommended – Little data on hazards of long-term exposure and on safe exposure levels – "Anaphylaxis-like" reactions after repeated use have been reported in other endoscopy application areas [33] – Little data on fixation behavior

Table 3 Advantages and disadvantages of orthophthalaldehyde (OPA).

In patients, residues of glutaraldehyde left after insufficient rinsing can cause colitis, abdominal cramps, and bloody diarrhea [33–38].

Other disadvantages of glutaraldehyde are coagulation and fixation of proteins and failure to eliminate atypical mycobacteria within standard contact times. The latter creates diagnostic problems in bronchoscopy and the risk of cross-infection in immunocompromised patients with, for instance, organisms of the Mycobacterium avium complex. This situation is further complicated by the emergence of glutaraldehyde-resistant mycobacteria [39].

Advantages and disadvantages of glutaraldehyde are listed in **Table 2**.

8.2.2. Orthophthalaldehyde (OPA)

Disinfectants based on orthophthalaldehyde (OPA) are offered as RTU solutions containing 0.55% of the active substance. Commercially available products can be used manually, in automated disinfection devices and in washer-disinfectors. Studies have shown better microbiological efficacy compared with glutaraldehyde. OPA requires longer exposure times to be effective against glutaraldehyde-resistant mycobacteria. It does not produce noxious fumes, it requires no activation, and is stable at a wider pH range of 3 to 9.

Exposure to OPA vapors may be irritating to the respiratory tract and eyes [30]. Use in a well-ventilated area and in closed containers with tight-fitting lids is recommended.

Advantages of OPA are its higher efficacy compared with glutaraldehyde and its long lifespan (2 weeks). Very accurate monitoring of the OPA concentration is always required.

There are some disadvantages of OPA, and its efficacy and properties need to be evaluated further. Data on safe exposure levels and the hazards of long-term exposure are scarce.

OPA causes coagulation and fixation of proteins. Exposure to the agent can lead to staining of linen, clothing, skin, instruments etc., by reaction with amino and thiol groups. Specific detailed instructions are necessary to ensure adequate rinsing of equipment. In other endoscopy application areas OPA has caused "anaphylaxis-like" reactions after repeated use [40].

Advantages and disadvantages of OPA are listed in **Table 3**.

8.2.3. Peracetic acid (PAA)

Disinfectants based on PAA and its salts are commercially available for endoscope reprocessing, as liquids or powder and as two-component systems comprising two liquids or liquid and powder. Depending on the composition, the products are used at room temperature or higher temperatures up to 56 °C. Concentrated products need to be diluted with water, in a ratio determined by microbiological testing according to European or local standards. The efficacy of PAA is strongly influenced by the pH value of the disinfecting solution. In the commonly used pH range (between 3 and 8.5) the efficacy is higher than that of glutaraldehyde.

Regarding staff safety, PAA is claimed to cause less irritation than glutaraldehyde and to be safer for the environment. Even though PAA is not believed to cause allergic reactions or asthma, there have been reports of skin, eye and respiratory irritation from PAA [30]. Adverse effects are strongly linked to the pH value of the disinfectant solution, with minimal effects observed in a pH range between 7.5 and 10.0. It would, however, seem unwise to state that PAA can be used safely without adequate ventilation or personal protective measures, especially in reprocessing. However in automated processing in a closed system, the pH value of the used solution is less relevant with respect to staff safety and to the environment.

PAA has the ability to remove hardened material in biopsy channels that has resulted from the use of glutaraldehyde, as demonstrated by surface spectroscopy. In the long history of PAA use in the food industry and medicine, no development of microorganism resistance has been reported; its broad spectrum of chemical reactivity suggests that microorganisms are unlikely to develop resistance to it.

One disadvantage of liquid PAA is that it is less stable than glutaraldehyde. The shelf-life of liquid products containing PAA is

Advantages	Disadvantages
– Fast high level disinfection and sporicidal activity – Preferably single-shot use – Depending on formula, in-use solutions are stable for 1–14 days – Environmentally friendly substance – No chemical cross-linking of protein residues	– Depending on pH value, irritant to skin, eyes and respiratory tract; strong odor of vinegar; ventilation is recommended – Material compatibility depends on the pH value and temperature; endorsement of compatibility with endoscopes and processor is required – Acid-related coagulation of proteins is possible, depending on pH value

Table 4 Advantages and disadvantages of peracetic acid (PAA).

Advantages	Disadvantages
– Fast high level disinfection and sporicidal activity – In-use solution stable for 7–14 days	– Irritant to skin, eyes, and respiratory tract; strong odor of chlorine; ventilation is recommended – Damage to endoscopes has been reported; endorsement of compatibility with endoscopes is required (an additional coating might be required with some types of endoscopes – manufacturer-specific) – Waste water restriction for chlorine compounds in some countries

Table 5 Advantages and disadvantages of chlorine dioxide.

between 12 and 18 months depending on storage conditions. The shelf-life of powdered products is 3 years.

Multiply used solutions require replacement between 24 h and 7 days. Very accurate monitoring of the PAA concentration is required.

Further disadvantages of PAA are its vinegary odour and corrosive action, depending on the formulation. Both properties are strongly linked to the pH value, temperature, PAA concentration, and the composition of the disinfectant (i.e. inclusion of anticorrosive agent, etc.). Damage to flexible scopes has been reported after disinfection with some brands of PAA. The oxidizing ability of PAA may expose leaks in the scope's internal channels, especially if it has been previously disinfected with glutaraldehyde, where biofilm might have covered minor perforations. PAA may also cause cosmetic changes of endoscope surfaces, but without any functional impairment.

It should be noted that various brands of disinfectants based on PAA are available with variations in effectiveness and side-effects. There are also on the market disinfectants based on PAA with various labelled claims, depending on composition and on the microbiological test procedure that has been applied to check microbiological efficacy.

Advantages and disadvantages of peracetic acid (PAA) are listed in ▶ **Table 4**.

8.2.4. Chlorine dioxide

Disinfectants based on chlorine dioxide are commercially available as two-component systems applicable in automated disinfection devices. Chlorine dioxide is more effective than glutaraldehyde.

Depending on the composition, disinfectants based on chlorine dioxide can be more damaging to the instrument and processor components than glutaraldehyde. Experience with chlorine dioxide has demonstrated discoloration of the black plastic casing of flexible endoscopes, but this change may be only cosmetic. If chlorine dioxide is used in automated disinfection devices, component contact times are likely to be much longer and, therefore, damage is even more likely. Chlorine dioxide is another possible alternative to glutaraldehyde, if approved by the instrument and processor manufacturers.

Advantages and disadvantages of chlorine dioxide are listed in ▶ **Table 5**.

8.2.5. Electrolytically generated disinfectants

Electrolytically generated disinfectants are produced on site by the electrolysis of sodium chloride solutions. The efficacy of the disinfectant is influenced by the concentration and ratio of oxidant constituents governed by the pH value. An advantage of these disinfectants is that commercially available systems at different pH levels are much more effective than glutaraldehyde. In addition electrolytically generated disinfectants have excellent user and patient safety profiles. A disadvantage of these disinfectants is that the biocidal effect is decreased in the presence of a heavy soil load. To ensure a full microbicidal effect, it is essential that items are cleaned thoroughly. Antimicrobial efficacy and materials compatibility are strongly influenced by the pH value and the oxidant concentration. Similarly to some peracetic acid-based products, electrolytically generated disinfectants are able to remove organic layer and biofilm from surfaces. Development of microorganism resistance has not been reported and the broad spectrum of chemical reactivity suggests that microorganisms are unlikely to develop resistance to it.

Electrolysed acid water (EAW) systems operate at pH ≤ 2.7, an oxidation–reduction potential (ORP) > 1000mV, and free released chlorine concentration (FRCC) 10 ± 2 ppm. The generation and use of EAW must operate at the same time in the same device. Since the pH and the oxidation–reduction potential are constantly monitored, this method minimizes the major disadvantage of electrolysed acid water, that is, its instability. In spite of its strong acidity, EAW rarely shows adverse effects on the human skin and mucosa, unlike hydrochloric acid and other solutions with the same acidity.

Electrolytically generated hypochlorous acid systems operate at pH 5.75 – 6.75 and ≥ 180 ppm of available free chlorine (AFC). Typically the disinfectant is produced and supplied on site via an external generator that directly supplies the washer-disinfectors. The generator controls disinfectant production, utilizing validated system monitoring that ensures only product complying with the specification is delivered to the washer-disinfectors. The generator controls pH, conductivity, power, and cell flow

Advantages	Disadvantages
– Fast high level disinfection and sporicidal activity – In-use solution is reusable as long as the generator works – In-use solution is nonirritant to skin, eyes, and respiratory tract	– Fast deactivation of in-use solution where residual organic load is present – Endorsement of material compatibility with endoscopes is required (an additional coating might be required with some types of endoscopes – manufacturer-specific) – Acid-related coagulation of proteins is possible, depending on pH value – Waste water restriction for chlorine compounds in some countries

Table 6 Advantages and disadvantages of electrolytically generated disinfectants.

rate, with each parameter having a specific tolerance range which is continually checked by the monitoring system. The disinfectant is safe to handle, requiring minimal personal protective equipment. It is nontoxic, nonsensitizing, nonirritating, and nonmutagenic.

Advantages and disadvantages of electrolytically generated disinfectants are listed in **Table 6**.

8.3. Rinse aid

A new procedure improves the drying of flexible endoscopes by adding a rinse aid into the final rinse water, based on surfactants that reduce the surface tension of residual water. The drying time can be reduced as well as the energy requirements of the process. As the rinse aid remains on the endoscope, toxicological issues must be assessed according to ISO 10993-1 (*Biological assessment of medical devices*).

8.4. Combination of products from different manufacturers

The combination of different product groups for cleaning and disinfection could cause compatibility problems. Therefore manufacturers' recommendations have to be followed at all times. Interactions can cause a change of colour of endoscope surfaces, or depositions or sedimentation on endoscope surfaces and inside washer-disinfectors and automated disinfection devices. In case of any interactions, the user should contact the manufacturers of the chemicals, the endoscopes, and the washer-disinfectors.

For example, detergents containing antimicrobial substances based on amine compounds should not be used in combination with glutaraldehyde. In some cases colored residues have been observed as a result of a suspected chemical interaction.

8.5. Change of products

If an endoscopy department plans to change detergents and/or disinfectants, the user must inform the service provider and the responsible persons/department for infection control and occupational health. The manufacturers need to provide compatibility evidence for washer-disinfectors, endoscopes, and chemicals. Unauthorised use may invalidate guarantees and/or service contracts.

As chemicals are important components of cleaning and disinfection, the reprocessing cycle has to be revalidated [3].

Staff need to be trained in the changed reprocessing procedure, regarding new products, contact time, concentration, and protection measures.

9 Reprocessing of endoscopes

9.1. Manual cleaning

9.1.1. Pre-cleaning in the endoscopy room

As soon as the endoscope is withdrawn from the patient, precleaning should begin. Before the endoscope is detached from the light source and video processor, detergent solution is sucked through the working channel and the air/water channel is flushed with water in order to remove debris and to check the correct functioning of the channel. The insertion tube is cleaned externally with a soft, disposable cloth/sponge and checked for any damages.

After the endoscope has been detached from the light source and video processor it is transported in a closed container to the reprocessing room to avoid environmental contamination.

9.1.2. Manual cleaning in the reprocessing room

The leak test must be performed according to the manufacturer's instructions, in order to check the inner and outer surfaces of the endoscope for any damage.

In the case of any leakage, the reprocessing procedure must be interrupted immediately and repair of the endoscope should be initiated. In such cases, the user should clearly mark the endoscope as "Not disinfected." The leak test should be performed before each reprocessing cycle.

Thorough manual cleaning with detergent remains an important step of the endoscope reprocessing procedure. This includes:

- Dismantling of all detachable parts of the endoscope such as suction and air/water valves, distal caps, and water bottle inlets.
- Cleaning of all external surfaces, valve ports and channel openings, using a soft, disposable cloth, suitable brushes and sponges
- Brushing of all accessible channels using flexible, purpose-designed brushes. The size and type of cleaning brush must be matched appropriately to size and type of endoscope channels, to ensure contact with channel walls. To ensure maximum effectiveness of cleaning and to avoid tissue carryover, ESGE and ESGENA recommend the use of single-use brushes as these have undamaged bristles without any tissue remnants from previous examinations. All reusable brushes must be thoroughly cleaned manually, followed by ultrasonic cleaning and decontamination (preferably sterilization) after each usage.
- Flushing of all lumens in order to remove organic material (blood, tissue, stool, etc.). All auxiliary water channels, wire channels, and balloon inflation channels (in endoscopic ultrasound [EUS] endoscopes and probes) have to be cleaned

according to manufacturers' recommendations, even if they have not been used in that examination.

Rinsing solution should not be reused.

It is important to make sure that all external and internal surfaces are completely wetted by the cleaning solution and are subjected to mechanical action.

With manual cleaning it is important to follow the contact time, temperature and concentration recommended by the manufacturer in order to ensure a sufficient effect of the cleaning solution.

After thorough manual cleaning the endoscope is ready for automated or manual reprocessing.

9.2. Reprocessing in washer-disinfectors

9.2.1. Definition and process basics for washer-disinfectors

Washer-disinfectors (also called automated endoscope reprocessors [AERs]) have become an essential part of most endoscope reprocessing areas as they ensure a validated and standardized reprocessing cycle and also reduce staff contact with process chemicals. The machine must be effective, safe, reliable, and able to cope with endoscope design and throughput.

According to the definition of EN ISO 15883, washer-disinfectors are intended to clean and disinfect medical devices, e. g. flexible endoscopes, within a closed system. Cleaning is an essential part of the reprocessing cycle. Therefore, washer-disinfectors that offer the relevant cycle steps (cleaning plus disinfection plus rinse) should be recommended for use.

The washer-disinfectors should fulfill the following basic criteria:

- Ensure complete irrigation of all scope channels including: biopsy, suction, air/water, auxiliary water and elevator channel
- Avoid cross-contamination with other reprocessing batches
- Offer a more reliable and reproducible decontamination procedure than manual processing
- Reduce the likelihood of eye, skin and respiratory exposure (closed system).

The most important and influential process parameters for achieving correct results are:

- water quantity and quality required for each cycle phase/step
- temperature during each cycle phase (minimum effective temperature)
- mechanical actions
- concentration of chemicals (minimum effective concentration)
- contact time during each cycle phase.

9.2.2. Process specifications for washer-disinfectors

According to the standard EN ISO 15883-4, washer-disinfectors may carry out the following cycle steps:

- *Leak testing:* monitoring the integrity of the scope to be reprocessed (no leaks that may endanger further use of the endoscope).
- *Flushing:* removal of residues from the external surfaces and the interior of the scope channel.
- *Cleaning:* removal off all visible dirt and residuals from scope surfaces and interior of scope channels, by means of specified detergents. Cleaning inside washer-disinfectors is done by water that must be pumped through the scope channel systems at specified temperatures for a specified time. The amount of detergent added during the cleaning phase must be monitored and should not go below the specified concentration range.
- *Rinse (optional, only if required)*: removal of residual cleaning process chemicals that could interfere with the subsequent disinfection stage.
- *Disinfection:* reduction of all bacteria, mycobacteria, fungi, yeasts, and viruses to a level such that patients will not be harmed at a later time.
- *Rinse (optional, only if required):* removal of chemical residues from the instruments/scopes that have been disinfected.
- *Final rinse:* a second rinse for removal of the chemical load from the instruments/scopes that have been disinfected. Recontamination of the disinfected scopes by use of rinsing water of inappropriate quality must be prevented.
- *Drying (optional).* Drying can be of two kinds:
  1. Drying in between examinations, which involves removal of residual fluid from outside surfaces and interior channels.
  2. Extended drying at the end of the working day in order to keep endoscopes safely stored at least overnight and to prevent recontamination from residual liquids or from environmental effects.

A variety of different functions of washer-disinfectors should be considered. They are:

- Monitoring of quantity of water supplied to washer-disinfectors
- Single or controlled multiple use of all process chemicals that are used during reprocessing cycles EN ISO 15883
- Dosage monitoring of all chemicals that are added during the reprocessing cycle
- Monitoring of specified process temperature profiles during all process phases
- Means of preventing mixing or wrong placement of process chemicals into the washer-disinfectors
- Automatic leak testing of endoscopes, including monitoring and control of critical overpressure situations in order to avoid damage to endoscopes
- Monitoring of flow through endoscope channels (flow control)
- Heating devices for fluids, to reach specified process temperature levels
- Independent control system that prevents escape of irritating or sensitizing process chemical vapors into the environment
- Trays and adapters for reprocessing of all compatible equipment
- A rinse water treatment system that prevents recontamination of processed instruments during rinsing
- Self-disinfection of water supply and water treatment components
- Optional thermal disinfection cycle for reprocessing of thermostable accessories
- Air-drying facilities to expel fluids and to dry the channels of the endoscope at the end of a cycle
- Documentation of all relevant endoscope and process data and recording of reprocessing reports
- A printout of cycle, disinfection parameters, and endoscope data that can be retained for quality assurance records
- A cycle counter and fault indicator
- Interfaces that may allow communication with hospital networks for process documentation.

Advantages	Disadvantages
– High level of standardization in reprocessing – Low risk of either patient or staff infection – Complete documentation – Full compatibility with latest European norms – Economic use of chemicals and other resources – More user-friendly – More reliable – Regular validation of full process will increase reliability – Separation between clean/dirty areas	– High cost – Dedicated user skills and knowledge still required – Added validation costs to be covered by users – More complexity and more training required – Without regular maintenance there is a risk of infection

Table 7 Advantages and disadvantages of reprocessing in washer-disinfectors.

9.2.3. Specific recommendations for washer-disinfectors

The use of washer-disinfectors does not remove the need for manual cleaning of the insertion tube, suction/biopsy channel, instrument tip, and valves. Manual cleaning (including brushing) of endoscopes and their accessories (valves, distal caps, etc) is mandatory.

Local reprocessing regulations must be followed. In some European countries, double cleaning in the washer-disinfectors is required before the disinfection stage can be initiated (i.e., France, Austria).

9.2.4. Advantages and disadvantages of washer-disinfectors

These are summarized in **Table 7.**

9.3. Reprocessing in automated disinfection devices

9.3.1. Definition and process basics for automated disinfection devices

Automated disinfection devices are intended to disinfect flexible endoscopes in a closed system after manual cleaning, thus their cycle includes disinfection and rinse steps but not cleaning.

There is a great variety of automated disinfection devices on the market. All of these perform the disinfection step and final rinsing step. Additionally, some automated disinfection devices offer the following:

- integrated leakage testing
- automated rinsing step using water
- optional drying step after the final rinsing.

A manual leakage test and manual cleaning must be done after manual pre-cleaning (see section 9.1.) and before the endoscopes can be placed in the automated disinfection devices for further disinfection treatment. As these disinfection devices do not have an integrated cleaning phase, it is even more important for the user to carefully clean the endoscope manually. The machine must be effective, safe, reliable and able to cope with the endoscope design and the throughput.

Automated disinfection devices must fulfill the following basic criteria:

- Ensure complete irrigation of all scope channels, including the biopsy, suction, air/water, auxiliary water and elevator channels.
- Avoid cross-contamination of other reprocessing batches
- Offer a more reliable and reproducible decontamination procedure than manual processing
- Reduce the likelihood of eye, skin, and respiratory exposure for patients and hospital staff to the process chemicals (closed system).

9.3.2. Process specifications for automated disinfection devices

Automated disinfection devices usually have the following major features, which may vary significantly among devices.

- Monitoring for renewal of disinfectant solution
- Heater to keep disinfectant solution at specified temperature.
- Adapters for reprocessing of all compatible equipment
- A rinse water treatment system that prevents recontamination of processed instruments during rinsing
- Self-disinfection of water supply and water treatment components
- Printer interface for documentation of the disinfection data
- Fault indicator.

9.3.3. Specific recommendations for automated disinfection devices

Numerous manual steps are necessary before an endoscope can be processed in automated disinfection devices. Manual precleaning is mandatory, as with washer-disinfectors.

The cleaning stage must be done manually. There needs to be assurance that detergent residues will be removed effectively from the endoscope before it is reprocessed in the automated disinfection devices. Residues may interfere with the disinfectant solution in the automated disinfection devices.

The most important and influential process factors for achieving suitable results are as follows:

- Users must comply strictly with the endoscope manufacturer's instructions for pre-treatment of the instruments.
- In the case of reuse of disinfectant solutions, regular efficacy tests are required (according to the instructions of the manufacturer of the chemicals and depending on the frequency of use).
- Manual drying must be adequate.

9.3.4. Advantages and disadvantages of automated disinfection devices

These are summarized in **Table 8.**

9.4. Manual reprocessing of endoscopes

9.4.1. Definitions and process basics for manual reprocessing

All steps of the reprocessing cycle are performed manually (see **Fig. 1** and section 9.1).

9.4.2. Process specifications for manual reprocessing

Manual reprocessing of endoscopes gives reliable results, provided that well-trained staff perform the reprocessing conscientiously according to defined standard operating procedures (SOPs). The SOP should take into account the different types of

Advantages	Disadvantages
– Low purchase costs compared with washer-disinfectors – Lower workload compared with full manual reprocessing	– Lack of standardization of manual cleaning – In case of reuse of disinfectant, efficacy problems and cross-contamination need to be considered – Increased workload of routine testing (i. e. disinfectant efficacy testing) – Traceability and documentation is more time-consuming – More complexity and more training required – Without regular maintenance there is a risk of infection

Table 8 Advantages and disadvantages of reprocessing in automated disinfection devices.

endoscope used in the department. It should be documented and be easily available to the staff who are carrying out the procedures.

Cleaning. Manual pre-cleaning and cleaning, including brushing, is mandatory to remove all gross debris from internal and external surfaces. The procedure is described in section 9.1.

Disinfection. In manual disinfection the endoscope must be immersed completely. All channels must be filled with disinfectant. With manual disinfection it is important that the manufacturer's recommendations regarding correct concentration, temperature, and contact time are followed, to ensure adequate disinfection.

The disinfecting solution should be freshly prepared at least on a daily basis. If the disinfectant is a concentrated product, it should be diluted with filtered water or water of drinking quality, to the correct dilution. If the disinfecting solution is used for longer than 1 day, based on the manufacturer's recommendation, the active ingredient content should be checked at least daily as the concentration can be lowered by:

- decomposition of the active substance
- adsorption of the active substance on surfaces
- inactivation of the active substance by reaction with protein
- dilution of the disinfecting solution by rinse water remaining in the endoscope from the previous reprocessing step.

Note: Up to 50 ml of solution can remain in an endoscope (depending on endoscope type) if the solution is not removed by compressed air.

Final rinsing. The disinfecting solution must be rinsed off from the internal and external surfaces of the endoscope.

- The endoscope is rinsed and the channels flushed, with water of at least drinking quality, to remove the disinfecting solution.
- Sterile water is preferable for the final rinse.
- National requirements regarding water quality must be taken into account.
- The rinse water is discarded after each use/cycle.

9.4.3. Advantages and disadvantages of manual reprocessing

These are summarized in **Table 9.**

9.5. Drying, storage, and reuse of endoscopes

Before storage, thorough drying of endoscopes is necessary to prevent the growth of waterborne microorganisms.

Endoscopes are not usually completely dried in between endoscopic procedures. Washer-disinfectors offer a short drying cycle which is used between endoscopic procedures and an intensive final drying cycle to be used at the end of the endoscopy clinic. Nevertheless staff should check the quality of the final drying and if necessary, dry the endoscope manually with compressed filtered air before storage.

With manual drying the external parts of the endoscope, especially the control body, light/video connectors, and plugs, should be dried carefully. Endoscope channels should be dried with compressed filtered air.

According to some guidelines, flushing with 70% – 90% alcohol or isopropyl alcohol is recommended for drying of endoscope channels [41,42], but this should only be used at the end of a clinic as residual alcohol poses a risk during electrosurgical procedures. There is no clear evidence that flushing with alcohol is effective in either drying endoscopes or preventing the proliferation of waterborne bacteria [26,43]. Due to the fixative properties of alcohol, its use is not recommended in some countries.

Flexible endoscopes should be stored vertically in well ventilated cupboards. Specially designed cupboards are commercially available which assist the drying process by means of special ventilation methods, using filtered air or container systems.

Valves should be disconnected as they may block the air flow through the endoscope channels. Valves and distal caps should be stored separately but with the endoscope.

Valves (including rinsing valves) should stay with a named endoscope as a set, to prevent cross-infection and enable full traceability [23].

Local policies must be in place that define for how long a reprocessed endoscope can be used before it needs re-disinfection.

If a storage cabinet is used, a risk assessment will determine the period over which a disinfected endoscope can stored and reused without further reprocessing.

There is a new procedure to improve the drying of flexible endoscopes. This involves adding a measured amount of a medical rinse aid into the final rinse water. The characteristics of this new procedure remain to be examined.

10. Quality assurance

Quality assurance processes and standards vary from country to country and practitioners need to comply with national regulations. The ESGE–ESGENA guideline may help in the development of such regulations in countries where they do not exist at present, or may help individual endoscopy departments in developing local standards and protocols.

10.1. Documentation

The complete reprocessing cycle of every endoscope should be documented.

- Each reprocessing step is recorded manually or electronically, including the name of the person undertaking each step.

Advantages	Disadvantages
– Easy to establish without any major investments	– Validation not possible, but standardization for all reprocessing steps is possible – Staff exposure to process chemicals – Increased workload, because staff are involved in each reprocessing step – In case of reuse of disinfectant, efficacy problems can be expected – Traceability and documentation is more time-consuming – Increased risk of infection and re-contamination

Table 9 Advantages and disadvantages of manual reprocessing.

- The process parameters of the washer-disinfectors and automated disinfection devices are documented by printouts or electronically, to show that the reprocessing cycle was successful and complete.
- All endoscopes have a record of their decontamination such that they are ready for use on patients.
- The decontamination record is documented in the patient's notes.

10.2. Maintenance of washer-disinfectors and automated disinfection devices

Washer-disinfectors and automated disinfection devices may pose an additional infection risk. Therefore they must:

- be cleaned and maintained on a daily basis according to manufacturer's recommendations
- have regular engineering maintenance
- have regular microbiological surveillance.

Washer-disinfectors and automated disinfection devices must be capable of self-disinfection and should use water of at least drinking quality.

The cleaning solution and rinsing water in washer-disinfectors and automated disinfection devices should not be reused.

Regular maintenance is essential in order to ensure and maintain appropriate performance in washer-disinfectors and automated disinfection devices; the manufacturers are responsible for specifying the required maintenance.

10.3. Process validation and microbiological surveillance

Manufacturers are responsible for providing information and instructions on how to validate the reprocessing process.

- Process validation for washer-disinfectors can be performed according to the following:
- EN ISO15883 parts 1, 4, and 5 [9,27,28]
- *ESGE/ESGENA guideline for process validation and routine testing for endoscope reprocessing in washer-disinfectors, according to the European standard prEN 15883 parts 1, 4 and 5* [3]
- *ESGE–ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy* [4].

Process validation for disinfection devices must be done according to the manufacturer's instructions.

Periodic microbiological surveillance testing should be performed according to the *ESGE–ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy* [4]

Routine quality assurance of the whole endoscope reprocessing system must be established, that covers the endoscopes, washer-disinfectors, and water supply used in endoscopy. As a point of reference, the ESGE–ESGENA Guideline Committee recommends routine testing at intervals no longer than 3 months [4]. Endoscopes, washer-disinfector, and the water used in endoscopy must be tested at the same time, in order to identify a cause of infection.

10.4. Outbreak management

If any contamination is found it is the responsibility of the clinical service provider to take the suspect piece of equipment out of service (e.g. endoscopes, washer-disinfector, accessories, etc), until corrective actions have been taken and satisfactory results have been achieved [3,4].

11. Reprocessing of endoscopic accessories

11.1. General recommendations

Endoscopic accessories are used for diagnosis and treatment during endoscopic procedures. They are available as reusable and single-use devices. Manufacturers have to give clear instructions on how to reprocess reusable accessories (EN 17664). The trend to employing single-use devices is increasing in many western European countries.

Reusable accessories should be reprocessed appropriately. If this is technically not possible (e.g. in the case of balloons or bougie dilators), they should be employed as single-use devices.

In some countries single-use accessories are preferred as they

- Prevent cross-infection in both patients and in staff
- Avoid potential staff injuries during cleaning
- Ensure a fully functioning accessory each time (providing a good cut, etc)
- Make the use of ultrasonic cleaning equipment obsolete/unnecessary and therefore, also reduce the risk of cross-infection from contaminated solutions, and of potential release of harmful vapors.

Local recommendations must be respected.

11.2. Process specifications

After manual pre-cleaning with dismantling and brushing, endoscopic accessories should be cleaned in an ultrasonic cleaner. Further reprocessing (see **Fig. 2**) can be done either

- manually
- using a washer-disinfector, or
- with sterilization in central sterilization departments.

11.2.1. Manual cleaning

Manual cleaning is the most important step in the removal of organic material from accessories. This includes thorough cleaning by:

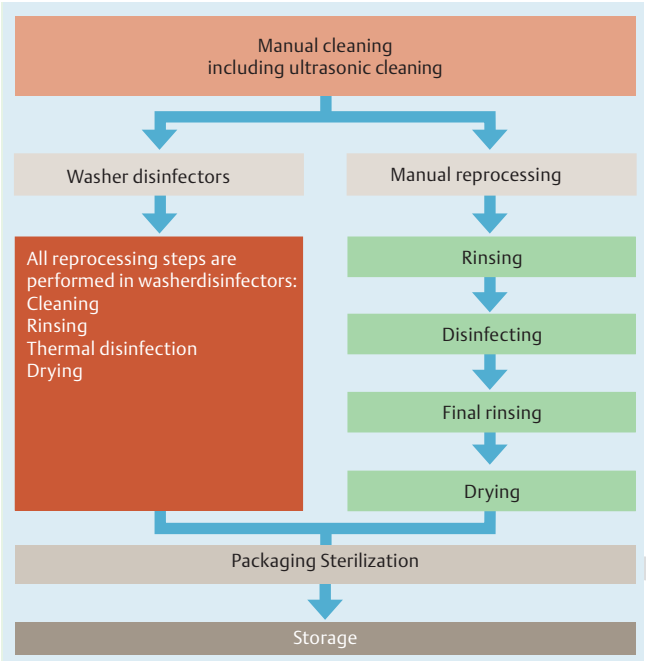

Fig. 2 Reprocessing of endoscopic accessories.

- Dismantling of accessories as far as possible (follow manufacturers' recommendations)
- Cleaning of external surfaces with a soft, disposable cloth/sponge and brushes
- Thorough brushing of biopsy forceps' cups
- Flushing all available channel lumens
- Ultrasonic cleaning
- Rinsing.

Ultrasonic cleaning is essential for the removal of debris from inaccessible areas of complex accessories. The tray of the ultrasonic cleaner should not be overloaded, in order to avoid ultrasound "shadows" or dead space. Ultrasonic cleaning must be performed before any disinfection or sterilization step. The use of a medical grade ultrasonic cleaner with a frequency range over 30 kHz (38 to 47 kHz) and a maximum operating temperature of 45 °C is recommended.

Accessories should be cleaned manually immediately after use to prevent any body fluids or debris drying on the instruments as this might cause ineffective reprocessing or malfunction. If immediate reprocessing is not possible, accessories should be placed in detergent.

The water quality available in the endoscopy unit should be specified.

11.2.2. Reprocessing in washer-disinfectors

For the reprocessing of accessories, thermal disinfection programmes are recommended (EN ISO 15883). Some washer-disinfectors for flexible endoscopes offer special programmes for heat-stable accessories. Washer-disinfectors for surgical instruments, according to EN ISO 15883-2, also offer loading systems and programs for heat-stable accessories.

11.2.3. Manual reprocessing

If reusable accessories are reprocessed manually, manual cleaning and ultrasonic cleaning are the most important steps (see section 11.2).

In some countries, such as Germany, disinfection is recommended as an additional step after ultrasonic cleaning in order to reduce the germ load before sterilization and for staff protection purposes [10]. In other countries, thorough rinsing and drying is done before the accessories are sterilized [23].

The detailed protocol for manual reprocessing of endoscopic accessories is listed in **Appendix 4.**

11.2.4 Sterilization

After thorough rinsing and drying, endoscopic accessories should be packed according to EN 868 [44] and sterilized according to European sterilization standards (e.g. EN 285 [45]) in line with manufacturers' instructions (recommendation: steam autoclave, pre-vacuum, 134 °C).

11.2.5. Storage

Endoscopic accessories should be stored in a closed cupboard. Before use, the sterilization package should be checked for any damage and for expiry date (EN 868).

11.3. Specific recommendations

11.3.1. Biliary and pancreatic procedures

All accessories used in the biliopancreatic duct system must be sterile. Reusable devices should be autoclavable. Balloons cannot be sterilized for technical reasons. The use of reprocessed (i.e. disinfected) balloons carries a risk of serial contamination of the biliopancreatic ducts.

11.3.2 Injection needles

Injection needles should be used once only. Under no circumstances should injection needles be reprocessed. ESGE and ESGENA recommend the use of disposable needles for several reasons:

- Dismantling of needles is dangerous for endoscopy personnel
- The narrow lumen is difficult to clean
- The needles are likely to be contaminated with blood
- The types of patients in whom they are used are often infectious.

This is in line with the recommendations for hypodermic needles.

11.3.3 Biopsy forceps

There is a clear trend towards employment of single-use biopsy forceps, despite studies having shown that it is possible to effectively reprocess and sterilize biopsy forceps [46].

11.3.4. Water bottles and their connectors

In addition to the endoscopes themselves, water bottles can be a source of endoscope contamination. This can be caused by inadequate cleaning of water bottles, lack of sterilization or use of tap water instead of sterile water [47].

Therefore, water bottles and connecting tubes must be cleaned and sterilized on a daily basis. The water bottles should be filled with sterile water and changed after each endoscopy session. Additionally, testing of water bottles should be included in regular quality control [4, 23, 47].

Competing interests: None

Appendix 1: Manual cleaning of flexible endoscopes

▼

Step 1. Pre-cleaning

Before the endoscope is detached from the light source and/or video processor

- Suck detergent through the working channel (minimum 250ml).
- Ensure that the working channel is not blocked.
- Flush the air/water channel with water from the water bottle.
- Use rinsing valves if available.
- Wipe down the insertion tube with a soft, disposable cloth/sponge.
- Check the outer surface of the endoscope for any damage.
- Detach the endoscope from the light source and/or video processor.
- Transport the endoscope in a closed system to the reprocessing room.

All further reprocessing steps must be performed in the reprocessing room.

Step 2. Leakage test

- Dismantle all detachable parts of the endoscope, e.g. suction valves and air/water valves, distal caps and water bottle inlets.
- Attach a soaking cap if necessary.
- Before starting the cleaning step, perform the leakage test according to manufacturer's instructions in order to check the inner and outer surfaces of the endoscope for any damage.

Note: If the leakage test is positive, the reprocessing procedure must be interrupted immediately and repair of the endoscope must be initiated.

Step 3: Manual cleaning

- Immerse the endoscope completely in water with detergent.
- Fill all channels with cleaning solution. Use the endoscope-specific adapters to ensure complete filling/rinsing with detergent.
- Clean all external surfaces, valve ports, and channel openings, using a soft, disposable cloth/sponge, and brushes. The distal end is brushed with a soft toothbrush and special attention is paid to the air/water outlet nozzle and the bridge/elevator where fitted.
- Brush all accessible channels with a flexible, purpose-designed brush. Appropriately sized brushes for each channel should be used to ensure good contact with the channel walls. The brush must be passed through each channel several times until clean and the brush itself must be cleaned in detergent with a soft toothbrush each time it emerges.
- Brushing/cleaning should be done with the endoscope completely immersed in the fluid in order to avoid splashing of contaminated liquids.
- Valves and distal caps must also be cleaned according to the manufacturer's instructions (mainly in the same way as the endoscope but additionally using an ultrasonic bath).

Note: Concentrations and exposure times should be in line with the manufacturer's instructions.

Step 4: Rinsing

- Rinse all outer surfaces and all channels by flushing with water followed by air to expel as much fluid as possible prior to disinfection. The rinsing removes detergent residues and avoids interactions between detergents and disinfectants.
- Drain, disinfect and rinse the container/basin before the next reprocessing procedure.

Appendix 2: Reprocessing of flexible endoscopes in washer-disinfectors and automated disinfection devices

▼

Thorough manual cleaning is a prerequisite for effective disinfection. Therefore, manual cleaning including brushing must always be done before automated reprocessing is performed. The standard cleaning procedure for flexible endoscopes, steps 1–4 of Appendix 1: Manual cleaning of flexible endoscopes, must be done before a washer-disinfectors is used.

Step 5: Loading of washer-disinfector

- Load the basket, immersion trays or tank of the washer-disinfector in accordance with the manufacturer's recommendations.
- Attach channel connectors/separators to ensure complete and thorough irrigation of all lumens.
- Ensure that all channels are connected. The specific design of the machine must be taken into account.
- Valves and distal caps must be placed into a special basket.
- Remove gloves and close the washer-disinfectors.

Step 6: Reprocessing

- Select and start the cycle.
- After completion of the automated cycle, ensure that all cycle stages have been completed in accordance with set parameters.
- Open the washer-disinfector and remove the endoscope.

Step 7: Drying and storage

- Dry the endoscope externally and flush each channel with air. The drying process may be supported by flushing 70% alcohol through the endoscope channels.
- If there is to be further use, wipe the eyepiece and light guide connector as well as the plugs, before connecting the endoscope to the light source.
- Fit the disinfected and rinsed valves. The endoscope is now ready for use again.
- Before storage, the endoscope channels and outer surfaces must always be dried completely, in order to prevent the growth of microorganisms.
- Endoscopes should be stored vertically in a well ventilated storage cupboard.
- Valves should not be connected as this might block the air ventilation in the endoscope channel. Valves and distal caps should be stored separately next to the endoscope.

Appendix 3: Manual reprocessing of flexible endoscopes

Thorough manual cleaning is a prerequisite for effective disinfection. Therefore manual cleaning must always be done before disinfection is performed. Steps 1–4 detailed in Appendix 1: Manual cleaning of flexible endoscopes must always be done before disinfection.

Step 5: Disinfection

- After thorough manual cleaning, including brushing of all accessible channels, the endoscope is immersed completely in disinfectant solution.
- Fill all endoscope channels completely with disinfectant. Use the endoscope-specific rinsing adapters to ensure complete contact with disinfectant and to avoid any dead spaces.
- Valves and distal caps must be disinfected with the endoscope.
- Manufacturers' recommendations must be followed with regard to concentration and contact time of the disinfectant.

Step 6: Rinsing

- Rinse all outer surfaces and all channels by flushing with water to remove all traces of disinfectant.
- Rinse all valves and distal caps under water as well.
- The water must be of at least drinking water quality and should be free of pathogens such as *Pseudomonas aeruginosa*. If necessary, filtered water may be used for rinsing.

Note: Always discard the rinse water after each use in order to avoid any recontamination.

Step 7: Drying and storage

- Dry the endoscope externally and flush each channel with air. The drying process may be supported by flushing 70% alcohol through the endoscope channels.
- If there is to be further use, wipe the eyepiece and light guide connector as well as the plugs, before connecting the endoscope to the light source.
- Fit the disinfected and rinsed valves. The endoscope is now ready for use again.
- Before storage, always dry the endoscope channels and outer surfaces completely in order to prevent the growth of microorganisms.
- Endoscopes should be stored vertically in a well ventilated storage cupboard.
- Valves should not be connected as this might block the air ventilation in the endoscope channel. Valves and distal caps should be stored separately next to the endoscope.

Appendix 4: Manual reprocessing of reusable endoscopy accessories

Step 1: Cleaning

- Disconnect and dismantle accessories as far as possible.
- Immerse accessories in detergent solution immediately after use.
- Clean the single components of the devices externally using a soft cloth/sponge, and brushes.
- Brush or clean with the accessories completely immersed in the fluid, in order to avoid splashing of contaminated liquids.
- Inject detergent solution into all accessible lumina to remove secretions and debris (at least 10–20 ml solution in each lumen).
- Ensure that all lumina are flushed completely to avoid air blockages.
- Remove the instruments from the detergent solution.

Notes:

- All types of detergents recommended for reprocessing of medical devices can be used for cleaning endoscopy accessories. Compatibility of materials must be respected. Instructions from the manufacturers of the process chemicals must be complied with.
- Aldehydes cannot be used for cleaning steps because they denature and coagulate protein, thus fixing it, and this may impair cleaning.
- Cleaning must be done before disinfection.
- The water quality available in the endoscopy unit should be specified.

Step 2: Ultrasonic cleaning

- Use a medical grade ultrasonic cleaner with a frequency range over 30kHz (38 to 47kHz) and a maximum operating temperature of 45 °C, following the manufacturer's instructions.
- Ensure that the detergent used is a non-foaming solution, suitable for manual cleaning as well as for ultrasonic cleaning.
- Renew the cleaning solution at least daily or more frequently if the solution is contaminated.
- Ensure that the tray is large enough and deep enough to allow for complete immersion of the devices.
- Load the basket/tray of the ultrasonic cleaner with the dismantled and pre-cleaned accessories.
- Avoid any ultrasound "shadows" or dead spaces where ultrasound waves cannot act. Do not overload the tray.
- The instrument should be coiled with a diameter of not less than 15–20 cm, in accordance with manufacturer's instructions.
- Flush all channels and lumens completely again with at least 10 ml of detergent solution, to avoid air blockage.
- Follow the instructions of both the manufacturer of the ultrasonic cleaner and the manufacturer of the device.
- Cover the ultrasonic cleaner with a lid.
- Leave the accessories in the ultrasonic cleaner and complete the recommended contact time for ultrasonic cleaning, following the manufacturers' instructions for the devices, the ultrasonic cleaner and the detergents.
- Remove the accessories from the ultrasonic cleaner.
- Flush all channels with air to remove excess fluid.

Notes:

During ultrasonic cleaning the temperature can range from 40 °C to 60 °C. Proteins can be fixed at higher temperatures. When using enzymatic detergents ensure that the temperature is not over 45 °C, as compatible with detergent efficacy.

The temperature in the ultrasonic cleaner should be monitored.

Step 3: Rinsing

- Transfer the cleaned accessories to a bowl or tray containing water of at least drinking quality and renew the water after each rinsing cycle.

- Flush all lumina completely and thoroughly in the water to remove detergent residues. Flush the lumina with at least 20 ml water.
- Rinse external surfaces thoroughly, using water of at least drinking quality, to remove chemical residues.
- Remove the devices from the water.
- Drain or aspirate all lumina with air to remove residual rinse water.

Step 4: Drying

- Dry the external surfaces with a non-shedding cloth and compressed air.
- Dry each lumen completely with compressed air.
- Dry all coiled accessories in a hanging position to support the drying procedure.
- Assemble the accessories and check their correct functioning.

Step 5: Sterilization

- Put the accessories into sterile packaging for special instruments.
- Select the appropriate adequate sterilization procedure for the thermostable and thermolabile instruments in accordance with manufacturers' instructions (general recommendation: steam autoclave, pre-vacuum, and national laws).
- After completion of the sterilization cycle, ensure all cycle stages have been completed in accordance with set parameters.
- Check the sterile packaging for any damage and check the sterilization indicators.

Step 6: Storage

- Store sterilized instruments (in the sterile packaging) in a closed cupboard, protected from dust, humidity, and temperature fluctuation.
- Follow instructions concerning the durability of the sterile packaging.

Appendix 5: Reprocessing of endoscopic accessories in washer-disinfectors and automated disinfection devices

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As an additional step, washer-disinfectors may be used. Before this is done, pre-cleaning, ultrasonic cleaning and rinsing must be completed. Steps 1 to 3 of Appendix 4: Manual reprocessing of reusable endoscopic accessories.

Step 4: Loading of the washer-disinfector

- After thorough cleaning as described above, load the basket, immersion trays, or tank of the washer-disinfector in accordance with the manufacturer's recommendations.
- Attach connectors to ensure complete and thorough irrigation of all lumina.
- Ensure that all lumina are connected; the specific design of the machine must be taken into account.
- Handles, coils, or wires must be fitted into a special basket.
- Remove gloves and close the washer-disinfector.

Step 5: Reprocessing

- Select and start the cycle.
- After completion of the cycle, ensure that all cycle stages have been completed in accordance with set parameters.
- Open the washer-disinfector and remove the accessories.
- Dry the accessories if necessary with a non-shedding cloth.
- Dry each lumen with compressed air.

To complete the cycle, follow steps 5 and 6 of Appendix 4: Manual reprocessing of reusable endoscopic accessories.

Institutions

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[6] CBC (Europe) Ltd., MILAN Branch, Nova Milanese (MI), Italy
[7] PENTAX Europe GmbH, Service Division, Hamburg, Germany
[8] Sterilox Endoscopy, PuriCore International Limited, Stafford, UK
[9] Microbiology and Hygiene Department, Chemische Fabrik Dr. Weigert GmbH & Co. KG, Hamburg, Germany

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