

E.S.G.E. Guidelines

Guidelines on Cleaning and Disinfection in GI Endoscopy

Foreword

Since 1994, the Guidelines Committee has worked mainly on cleaning and disinfection of endoscopes and accessories. This important topic has been the subject of numerous meetings including nurses, industrial representatives and microbiologists.

Our goal has been to obtain a safely reprocessed endoscope at reasonable cost. We have taken into account that the ESGE Guidelines are circulated in countries with varying economic possibilities. The ESGE Guidelines are a strong recommendation but, within each country, endoscopists, nurses and hospital administrations have to comply with local regulations.

For these new guidelines, we have added a detailed technical protocol for the daily work of nurses and assistants, as we have been aware of multiple local variations in the use of general guidelines.

The close co-operation between the ESGE and ESGENA is a guarantee of efficacy and safety in the search for our main goal: high quality digestive endoscopy.

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Introduction

This document 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. It is the direct responsibility of users to follow these guidelines. These guidelines were prepared by consensus of microbiologists, endoscopists, nurses and representatives of the biomedical industry.

At all times, it is important to follow the manufacturers instructions and to comply with national law.

Patients undergoing digestive endoscopy should be examined and treated without risk of transmission of infection or side effects that may result from inadequately reprocessed endoscopic equipment (e.g., harm from residual chemicals on inadequately rinsed accessories).

The aim of these European Society of Gastrointestinal Endoscopy (ESGE) Guidelines is 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.

All reprocessing should be carried out by specially trained staff in purpose-designed environment. It is the responsibility of the healthcare provider to ensure that adequate facilities for reprocessing are available. Regular quality control and the institutions adherence to validated reprocessing procedures is the responsibility of both endoscopic and healthcare providers and should be monitored by the hospital based hygiene/cross-infection control department or an external organisation.

Endoscopy-Related Infections

Microorganisms may be spread by inadequately reprocessed equipment from one patient to another or from patients to staff members. Bacterial infections have been acquired during endoscopy, such as Salmonella and Pseudomonas. Viral diseases such as hepatitis B and hepatitis C have also been transmitted during endoscopy.

Patients with immune deficiency syndromes or severe neutropenia and those undergoing immunosuppressive chemotherapy or who have artificial cardiac valves have an increased risk of infection. Diagnostic endoscopic retrograde cholangiopancreatography and all therapeutic procedures carry a higher risk of infection. Patients harbouring clinically latent infections (hepatitis, HIV, TB, Salmonella, Helicobacter pylori) may not be aware of their carrier status, and therefore, all patients should be considered a potential risk.

Definitions:

ESGE - European Society of Gastrointestinal Endoscopy

ESGENA - European Society of Gastroenterology and Endoscopy Nurses and Associates

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Creutzfeldt-Jakob disease and endoscopy

Creutzfeldt-Jakob disease is a so-called prion disease. Little is known about the infectivity of prions. Transmission has been documented in patients treated parenterally with extracts from nervous tissue such as meninges and pituitary glands from infected patients. Transmission by the oral route probably occurs only after the ingestion of nervous tissue from infected animals.

Prions are difficult to detect and to eradicate. Attempts to do so using chemical or thermal methods would destroy the endoscope. Accordingly, if an endoscopy is requested in a patient with Creutzfeldt-Jakob disease, the procedure should be reconsidered.

Hazards to Endoscopic Personnel

Diseases may be transmitted from the patient to endoscopic personnel, so protection from direct contact with the endoscopes and accessories is essential. Gloves and aprons should be worn and protective masks and eye protection should be available to avoid exposure to blood or body fluids.

Protection against chemicals used in cleaning and disinfection procedures is of utmost importance in order to avoid toxic and allergic reactions. Separate purpose-designed rooms for cleaning and disinfection must be well ventilated and disinfectants should be used within a closed system.

Staff known to be disease carriers should avoid duties that could transmit infection to patients. It is recommended that all staff be offered vaccination against type B hepatitis.

Definitions

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

Cleaning: Removal of blood, secretions and debris from endoscopes and accessories.

Disinfection: Reduction of the number of viable microorganisms on a device, to a level appropriate for safe use on a patient where sterilisation of the device is not necessary. Disinfection may also be undertaken as a preliminary step to sterilisation, if necessary. Disinfection should be carried out immediately after cleaning and immediately prior to use.

Sterilisation: Validated process used to render a device free from all forms of viable microorganisms (ISO 11137).

Single-use accessories: Also called "disposable", these are provided in a sterile state ready for use. The opening of a sterile package implies immediate use, as is routine in surgery. After a single-use

device has been used, all materials should be properly disposed of. Under no circumstances should a single-use device be reused.

Reusable accessories: Reusable accessories should be sterilised. The sterilisation is carried out after proper cleaning, as detailed below. Manufacturers provide validated standard reprocessing parameters (temperature and time) for cleaning, disinfection and sterilisation.

Classification of Endoscopic Accessories for Reprocessing

The risk of cross-infection may vary, depending on the procedure. The European Society of Gastrointestinal Endoscopy recommends the following procedures:

1. Gastrointestinal Procedures

Wherever possible, the device used should be sterile; whether it is a single-use device and provided in a sterile state by the manufacturer, or a reusable one that has been sterilised (e.g. biopsy forceps, polypectomy snares). If it is not technically possible to achieve sterilisation (e.g. in the case of balloons or bougie dilators), the device should be subjected to disinfection.

2. Biliary and Pancreatic Procedures

All accessories used should be sterile. Reusable devices should be sterilisable. Balloons cannot be sterilised for technical reasons. The use of reprocessed (i.e. disinfected) balloons carries a risk of serial contamination of the biliary or pancreatic duct system, or both. The ESGE does not recommend the reuse of single use devices.

3. Injection Needles

Injection needles should be used once only. The European Society of Gastrointestinal Endoscopy recommends the use of disposable needles for several reasons: there is a danger to endoscopic personnel in dismantling needles, their narrow lumen is difficult to clean, they are likely to be contaminated with blood; and the type of patients in whom they are used are often infectious.

4. Prostheses

Prostheses should be used as recommended by the manufacturer.

Reprocessing of Endoscopes

The ESGE recommends the use of fully automatic washerdisinfectors.

Alternatively, a rigorous manual procedure must be employed. Before commencing with the reprocessing of endoscopes and endoscopy accessories, protective clothing must be put on (as appropriate: protective gloves, glasses/visor, face masks, aprons/examination coats) in order to avoid contact with infectious material and disinfectants or detergents.

A. Manual Cleaning

A.1. As soon as the endoscope is removed from the patient, the air/water channel must be flushed for 10 -15 seconds to eject refluxed blood or mucus. Detergent solution should be aspirated through the suction/biopsy channel to remove secretions and debris.

A.2. The endoscope should be immersed in water and detergent and cleaned externally. The outside of the instrument is washed with disposable sponges or swabs. 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. All valves are removed and washed. The biopsy channel opening and the suction part should be cleaned with a cotton bud.

A.3. Brushing through the suction/instrument channel and all accessible channels must be performed using a cleaning brush designed for that instrument. The brush must be passed through the channel several times until clean, and the brush itself must be cleaned in detergent with a soft toothbrush each time it emerges. First the instrument channel is cleaned by brushing at least three times, cleaning the brush between each brushing. Thereafter, pass the cleaning brush through the suction port and down the insertion tube until it emerges from the distal end at least three times, cleaning the brush each time as above. Then pass the cleaning brush from the suction part through the umbilical cord of the endoscope until it emerges from the suction connector at least three times, as above.

A.4. Rinse all the channels by flushing with water followed by air to expel as much air as possible prior to disinfection.

A thorough cleaning of the endoscope is a prerequisite for proper disinfection - manual or automatic.

B. Manual Disinfection

B.1. Disinfection must be carried out in a separate room with proper ventilation. Protective gloves, eye protection and aprons must be used and splashing avoided. The instrument should be fully immersed in 2 % glutaraldehyde or other chemical disinfectant of equal potency. All channels must be filled with disinfectant and soaked for not less than 10 minutes.

B.2. Rinsing of the instrument with water must be undertaken after disinfection, internally and externally, to remove all traces of disinfectant. The water must have drinking water quality. If necessary, filtered water may be used for rinsing.

B.3. Dry the endoscope externally and flush each channel with air. Wipe the eye piece and light guide connector as well as the plugs before connecting the endoscope to the light source. Fit the disinfected and rinsed valves and activate air/water channels as well the suction channel. The endoscope is now ready for use again.

Disinfection of the endoscopes should be performed before each session and between procedures.

C. Washer-Disinfectors

After a manual cleaning as described above, the endoscope may be disinfected automatically according to specification, attention being paid to temperature, flushing of all channels of the endoscope followed by a cleaning and a drying procedure. The duration of these reprocessing programmes is about 30 minutes.

Accessories (1)

A. Cleaning

- A.1.** Wash in detergent immediately after use.
- A.2.** Dismantle as far as possible.
- A.3.** Brush with cleaning brush or toothbrush.
- A.4.** Flush detergent through lumens of hollow components.
- A.5.** Use an ultrasonic cleaner for all accessories.
- A.6.** Rinse thoroughly in water of drinking quality.

(1) The ESGE and ESGENA Protocol follows as an Addendum

B. Sterilisation

Sterilisation can be achieved by steam autoclaving as per the manufacturers recommendations. Failure to follow the manufacturers recommendations may compromise sterility or the integrity of the device. Sterilisation can also be achieved with ethylene oxide, although this procedure is time-consuming and not readily available.

C. Storage

Sterile devices should be stored in individual packing. All non-sterilisable accessories should be disinfected immediately prior to use.

Care of Accessories and Instruments

Great care should be taken to avoid the use of defective or damaged accessories (e.g. biopsy forceps with kinks on the shaft) because such instruments may not operate properly and may also damage the endoscopes instrument channel, causing both hygienic and mechanical problems, with a consequent risk of incomplete reprocessing and even of serious damage to the endoscope itself.

Comment

Due to their nature, endoscopic accessory devices are not designed for repair in the event of breakage. Their repair is not recommended by the European Society of Gastrointestinal Endoscopy, since

the original properties may be altered with consequent risks to patients and danger of damage to endoscopes.

These guidelines draw attention to the necessity of increasing the number of endoscopic devices in each endoscopic suite, in order to ensure adequate availability, taking into account the reprocessing time required. The implementation of these guidelines does therefore have economic implications, increasing the cost of endoscopic procedures, but it is necessary in order to protect both patients and endoscopy personnel.

These guidelines have been revised by:

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Protocol for Reprocessing Endoscopic Accessories

Introduction

Today endoscopic procedures have become an important tool in the diagnosis and treatment of gastrointestinal diseases. In recent years the risk of infection has increased due to the increasingly invasive nature of the procedures. Moreover, more and more elderly people, patients with multiple diseases and patients with immune system deficiencies are being endoscoped than ever before. In order to prevent cross infections endoscopic control of infection measures have become increasingly important for both patients and the endoscopy staff. Therefore safe equipment reprocessing and careful maintenance of endoscopic equipment are the basis for an efficient prevention of infections programme in endoscopy.

During the last 10 years, the reprocessing of flexible endoscopes has become more and more standardised, facilitated by the increasing number of protocols that have been established for manual and automated cleaning and disinfection. Although there has been a more or less standardised disinfection protocol for endoscope reprocessing this has not been the case for endoscopic accessories, as different European membership countries permit a variety of reprocessing methods. Moreover, endoscopic accessories penetrating tissue require more stringent standards for reprocessing than endoscopes. Case reports about cross infections caused by inadequately cleaned and disinfected endoscopic accessories have highlighted the need for a standardised reprocessing protocol for endoscopic accessories.

In the light of these developments ESGE and ESGENA have worked together to produce this update of the ESGE Guidelines, which combines the three previous guidelines on hygiene and infection control in endoscopy. Included in the new guidelines is a detailed protocol for reprocessing of endoscopic accessories. Nurses and doctors may use these updated European Guidelines and the enclosed protocol as a reference manual while developing national versions or department specific protocols concerning hygiene and infection control. Furthermore, these guidelines should also raise awareness in endoscopy staff and service providers of the need for staff protection measures, necessary structural requirements and a standardised reprocessing protocol.

But however up to date at the time of publication, guidelines by their nature only reflect the current knowledge, opinions and research findings of experts in the field. Knowledge is not static and new evidence and research is constantly affecting and changing our practice. Guidelines do not abdicate the professional from being constantly vigilant, and it is everybody's responsibility to act in the light of newly produced evidence. Future research findings and new techniques and procedures may require amendments to or further editions of the current guidelines. Both ESGE and ESGENA will strive to respond to any such changes with appropriate recommendations.

Ulrike Beilenhoff

President of ESGENA

Standards for Manual Reprocessing of Reusable Endoscopic Accessories

Protective Measures

- Transfer contaminated devices immediately after use to the processing area and commence the disinfection process.
- Transport contaminated devices in a closed container from the endoscopy room to the reprocessing room, paying attention to protective measures concerning staff and environment.
- Before starting the reprocessing, put on protective clothing as appropriate:
 - chemically resistant gloves
 - protective glasses/visor - protective face masks
 - special examination gown or coat (long-sleeved, moisture-resistant) or plastic aprons with arms.

Step 1. Cleaning

- Disconnect and dismantle accessories as far as possible.
- Immerse accessories in enzymatic detergent solution immediately after use.
- Clean the single components of the devices externally by using a soft cloth, sponge and brushes.
- Perform brushing/cleaning under the water surface in order to avoid splashing of contaminated liquids.
- Inject detergent solution into all accessible channels and lumen to remove secretion and debris (at least 10 - 20 ml solution in each channel).
- Ensure that all lumen are flushed completely to avoid air blockage.
- Remove the instruments from the detergent solution.

Warning: Only specially trained personnel should carry out the reprocessing of endoscopic equipment - this applies both to routine as well as emergency endoscopy. Enzymatic-type detergent solutions are recommended for cleaning endoscopy accessories.

- Enzymatic detergents require a specific contact time, according to the manufacturers instructions.
- Aldehydes may not be used for cleaning steps because they denature and coagulate protein, fixing it and this may impair cleaning.
- Cleaning must take place 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 30 kHz (38 to 47 kHz) and a max. operation temperature of 45 8C, following manufacturers instructions.
- Use the same solution for the ultrasonic cleaner as for the cleaning step.
- 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 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 (maximum 10 devices per cycle and tray).
- Avoid any ultrasound “shadows”/dead spaces where ultrasound waves cannot act - therefore do not overload the tray.
- The instrument should be coiled with a diameter of not less than 15-20 cm, in accordance with manufacturers instructions.
- Flush again all channels and lumen completely with at least 10 ml detergent solution, to avoid air blockage.
- Follow the instructions of both the ultrasonic cleaner manufacturer and the devices manufacturer.
- Cover the ultrasonic cleaner with a lid.
- Leave the accessories in the ultrasonic cleaner and complete the recommended contact time for ultrasonic-al cleaning, following the manufacturers instructions for devices, the ultrasonic cleaner and detergents, (recommended ultrasonic cleaning time: 30 min). Remove the accessories from the ultrasonic cleaner.
- Flush all channels with air to displace excess fluid.

Warning:

- During ultrasonic cleaning the temperature can range from 40 to 60 8C. When using enzymatic detergents ensure that the temperature should not be over 45 8C, 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 drinking quality water without contamination and renew the water after each rinsing cycle.
- Flush all channels completely and thoroughly in the water to remove detergent residuals. Flush the channels with at least 20 ml water.
- Rinse external surfaces thoroughly using drinking quality water to remove chemical residues.
- Remove the devices from the water.
- Drain or aspirate all channels with air to express residual rinse water.

Step 4. Drying

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

Step 5. Sterilisation

- Put the instruments into sterile packaging for special instruments.
- Select the adequate sterilisation procedure for the thermal stabile and thermal labile instruments in accordance with the manufacturers instructions (recommendation: steam autoclave, pre-vacuum, 134 8C, 5 minutes or equivalent cycles) and national laws.
- After completion of the sterilisation cycle, ensure all cycle stages and parameters have been achieved.
- Check the sterile packaging for any damage and the sterilisation indicators.

Step 6. Storage

- Store sterilised instruments in the sterile packaging in a closed cupboard, protected from dust, humidity and temperature fluctuations.
- Follow instructions concerning the durability of the respective sterile packaging.

Standards for Automated Reprocessing of Endoscopic Accessories

As an additional step, an automated washer-disinfector may be used. Before this is done, pre-cleaning, ultrasonic cleaning and rinsing have to be computed. Follow steps 1 to 3 of the “Standards for manual reprocessing of endoscopic accessories.”

Step 4. Loading of an Automated Washer-Disinfector

- After thorough cleaning as described above load the basket, immersion trays or tank of the machine in accordance with manufacturers recommendations.
- Attach channel connectors 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.
- Handles, coils, or wires must be fitted into a special basket. - Remove the gloves and close the machine.

Step 5. Automated Reprocessing

- Select and start the cycle.
- After completion of the automated cycle, ensure that all cycle stages and parameters have been undertaken.
- Open the machine and remove the accessories.
- Dry the accessories if necessary, with a non-shedding cloth.
- Dry each channel with compressed air.

To complete the cycle, follow steps 5 - 6 of the “Standards for manual reprocessing of reusable endoscopic accessories” .

Further Information

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