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Safety in Minimal Access Surgery

EVIDENCE AND RECOMMENDATIONS

Editors
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CHAPTER 2

Sterilisation for Safe Minimal Access Surgery: Evidence and Recommendations

Ramanuj Mukherjee, Rohan Kundu

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INTRODUCTION

Sterilisation of surgical instruments has been the landmark event in surgical history that changed the fear of mortality and morbidity of surgical procedures to a safe 'miracle' event that could be reproduced even at basic healthcare facility. Every surgeon appreciates the breach in sterilisation increasing with every complex procedure getting surgical site infections.

In the United States, almost 47 million surgical procedures and about 5 million GI endoscopic procedures are performed every year. In every surgical procedure, sterile tissue or mucous membrane of the patient comes in contact with surgical instruments or device. All these procedures have a significant risk of introduction of pathogens leading to infection. Any compromise on disinfection or sterilisation of equipment carries a greater risk as it is associated with breach of host barrier, interpersonal transmission of disease (Hepatitis B etc.), and also transmission of environmental pathogenic microorganisms.

Disinfection and sterilisation are extremely important aspects of surgical care to ensure that instruments used in medical and surgical procedures do not transmit infectious pathogens to patients. Since all patient-care items do not need sterilisation, hospital policies must categorise the items accordingly into those requiring only cleaning, disinfection or complete sterilisation, depending upon their usage. Many studies have shown numerous outbreaks due to lack of compliance with updated guidelines for disinfection and sterilisation.

Laparoscopic procedures have demanded a high level of sterilisation with unique challenges as instruments are specialised and expensive with demand for disposable instruments being reused due to cost constraints. The following chapter is a brief summary of present disinfection and sterilisation practises as concerned for laparoscopy hardware and hand instrument.

DEFINITIONS

Standards of sterilisation, disinfection, and cleaning are not uniformly defined. However, the clinical and laboratory standard institution has come up with some recommendations according to minimum inhibitory concentration and are recently standardised by the International Organization of Standardization. The norms were first put forth in 2004 and newer guidelines were published in 2010.

Sterilisation: It is defined as a process of complete elimination or destruction of all forms of microbial life including both vegetative and spore forms. This can be done by different physical and chemical methods. There should be reduction of more than 106 log colony forming units (CFUs) of the most resistant spores within half time of a regular cycle.

Disinfection: It is defined as a procedure of complete elimination of vegetative forms of microorganisms except the bacterial spores from inanimate objects. There should be reduction of more than 103 log CFUs of microorganisms by this method without spores.

High-level disinfectant (HLD): It is used for shorter duration and should be able to kill 106 log microorganisms except spores.

Intermediate-level disinfectant (ILD): These disinfective agents act against *M. tuberculosis* and are mainly used for non-critical items contaminated with blood/body fluids.

Low-level disinfectant (LLD): These are used to remove the vegetative forms of bacteria, few fungi, and some enveloped viruses from the non-critical items, e.g., 3% hydrogen peroxide (H_2O_2), diluted glutaraldehyde, phenolics, quaternary ammonium compound, etc.

Decontamination and cleaning: Decontamination is the process of removal of pathogenic microorganisms

from objects so that they are safe to handle by the healthcare professionals. Cleaning is defined as removal of visible inorganic and organic materials from the surfaces and objects. It achieves minimum reduction of more than 1 log CFU of microorganisms.

Antisepsis: It is a process of removal of germs from the skin. When it is related to the patient's skin, it means disinfection of living tissue or skin, but when it is related to the healthcare worker, it means reduction or removal of transient microbe from the skin.

Germicide: It is an agent that destroys germs. It includes both antiseptics and disinfectants. The type of micro-organism it destroys is identified from the prefix (e.g., virucide, fungicide, bactericide, sporicide, and tuberculocide).

Chemical sterilant: These are chemicals used for a longer duration (3–12 hours) to destroy all forms of microbes, e.g., H_2O_2 (7.5%), glutaraldehyde (≥2.4%), per-acetic acid (PAA) (0.2%), ortho-phthalaldehyde (OPA) (0.55%), hypochlorous acid (400–450 ppm), and hypochlorite (650–675 ppm).

A RATIONAL APPROACH TO DISINFECTION AND STERILISATION

More than 30 years ago, a rational approach to disinfection and sterilisation of patient-care items and equipment was suggested by Earle H Spaulding. He classified the objects in such a clear and logical way that it has been retained and is still widely used by infection control professionals and others while selecting the proper method for disinfection or sterilisation.

According to Spaulding's classification, the type and standard of disinfection could be made out easily if instruments and items for patient care were classified as critical, semi-critical, and non-critical depending upon the degree of risk for transmission of infection involved in use of those items.

Critical Items

Objects that enter vascular system or sterile tissues must be sterile because any contamination could transmit disease. If contaminated with any microorganism, critical items carry a higher risk for infection. Critical items include cardiac and urinary catheters, surgical instruments, ultrasound probes, and implants that are used in sterile tissue or body cavities.

Items in this category should ideally be purchased as sterile or be sterilised using standard methods. Ethylene oxide (ETO) and H_2O_2 gas plasma can be used for the sterilisation of heat-sensitive objects.

Liquid chemical sterilants reliably sterilise only if cleaning is done prior to the treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and pH.

Semi-critical Items

These are items that come in contact of non-intact skin or mucous membranes. This category includes some cystoscopes, endoscopes, respiratory therapy and anaesthesia equipment, oesophageal manometry probes, laryngoscope blades, anorectal manometry catheters, and diaphragm fitting rings. These medical devices should ideally be free from all micro-organisms; however, a very small number of bacterial spores may be acceptable. Unbroken mucous membranes, such as those of the lungs and the gastrointestinal tract, are usually impervious to infection by common bacterial spores. However, they are susceptible to other organisms (e.g., bacteria, mycobacteria, and viruses).

Semi-critical items require minimal high-level disinfection using chemical disinfectant. OPA, glutaraldehyde, H_2O_2, and per-acetic acid with H_2O_2 are cleared by the Food and Drug Administration (FDA). If the factors influencing germicidal procedures are met, these are effective HLDs. Another factor that should be taken into consideration is the chemical compatibility of an item with disinfectant being used.

Cleaning before high-level disinfection removes enough pathogens to stop the transmission of infection.

Non-critical Items

These are items that come in contact with intact skin but not mucous membranes. Intact skin, as the first line of defence, is an essential barrier to most microorganisms; therefore, the sterility of patient-care items coming in contact with intact skin is 'not critical.'

Non-critical items are categorised into—non-critical environmental surfaces and non-critical patient-care items.

Examples of non-critical patient-care items are crutches, bedpans, blood pressure cuffs, and computers.

Most non-critical items may easily be decontaminated at the point of use and they do not require to be shifted to a central processing area. Patients have practically no risk in transmission of infectious agents through non-critical items if they are used as non-critical items and do not come in contact with non-intact skin and/or mucous membranes.

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SPAULDING'S CLASSIFICATION SCHEME
Determine the correct processing methods for items 1968 Earl Spaulding.[106-109]

Items that come in contact with	*Nature of item*	*Processing required*	*Examples*
Sterile tissue or vascular system	Critical	Sterilisation	Surgical instruments cutting endoscopic accessories, catheters, needles
Non-intact skin or mucous membranes	Semi-critical	*Sterilisation* or *minimum* of high-level disinfection	Respiratory therapy equipment, bronchoscopes, and GI scopes
Intact skin	Non-critical items	Intermediate-level disinfection, low-level disinfection, or cleaning	Tourniquets, blood pressure cuffs, linens

CDC RECOMMENDATIONS FOR DISINFECTION AND STERILISATION IN HEALTHCARE FACILITIES

A. Rationale

The actual goal of the Recommendations for Disinfection and Sterilization in Healthcare Facilities, 2008, is to reduce the rates of healthcare-associated infections through scientific use of both disinfection and sterilisation. The recommendations are categorised keeping in mind the scientific evidence, theoretical rationale, applicability, and federal regulations. Examples are incorporated in some recommendations to guide the worker; however, these examples do not define the only method of implementation of the recommendation. The CDC recommendations are defined in the following (Rankings) section.

B. Rankings

Category IA: Strongly recommended for implementation and are supported strongly by well-designed experimental, clinical, or epidemiologic studies.

Category IB: Strongly recommended for implementation and are supported by some experimental, clinical, or epidemiologic studies, and also by a strong theoretical rationale.

Category IC: Required by state or federal regulations. Because of state differences, workers should not assume that the absence of an IC recommendation implies the absence of state regulations.

Category II: Suggested for implementation and are supported by suggestive clinical or epidemiologic studies or by a theoretical rationale.

No recommendation: Unresolved issue. These include practices where insufficient evidence or no consensus exists regarding the efficacy.

C. CDC Recommendations for Disinfection and Sterilisation in Healthcare Facilities, 2008

1. *Cleaning of patient-care devices:*
   a. In hospitals, most cleaning, disinfection, and sterilisation of patient-care devices in a central processing department must be performed in order to control quality more easily (Category II).[1-3]
   b. Patient-care items must be meticulously cleaned with water and detergent, or with water and enzymatic cleaners before high-level disinfection or sterilisation procedures (Category IB):[4-21]
      i. Visible organic residue (e.g., the residue of blood and tissue) and inorganic salts must be removed by cleaning with cleaning agents that are capable of removing visible organic and inorganic residues (Category IB).[12-14,17,22-26]
      ii. Medical devices should be cleaned as soon as practical after use (e.g., at the point of use) because soiled materials get dried onto the instruments and make the removal process more difficult and render the disinfection or sterilisation process less effective or ineffective (Category IB).[16,27-32]
      iii. Manual (i.e., using friction) or mechanical cleaning (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers) should be performed (Category IB).[14,17,33,34]
      iv. If using an automatic washer/disinfector, one must ensure that the unit is used in accordance with the manufacturer's recommendations (Category IB).[7,35-37]
      v. One must ensure the compatibility of selected detergents or enzymatic cleaners with the metals and other materials used in medical instruments. Also, ensure that the rinse step is adequate for removing/cleaning residues to levels that will not interfere with subsequent disinfection/sterilisation processes (Category II).[2,21]
      vi. One must inspect equipment surfaces for breaks in integrity that would impair either cleaning or disinfection/sterilisation. Equipment that no longer functions as intended or cannot be properly cleaned and disinfected or sterilised should be discarded or repaired (Category II).[38]

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Summary of Recommendations for Cleaning of Patient-care Devices as in CDC Guidelines 2008

- Cleaning of medical devices using water, detergent, and enzymatic cleaners as soon as possible after use—*Category IA*.
- Mechanical—manual/automatic/ultrasonic cleaning as per manufacturer's guidance—*Category IB*.
- Central cleaning/processing unit—*Category 2*.

2. *Indications for sterilisation, high-level disinfection, and low-level disinfection*:
   a. For every device intended for patient use, all critical medical and surgical devices must have sterilisation, particularly if the device is intended for use in vascular system or normally sterile tissue (Category IA).[39-45]
   b. In case of semi-critical devices used in patient care such as endoscopes, which touch the skin or mucous membrane at minimum, high-level disinfection is necessary (Category IA).[6-8,17,20,46-58]
   c. For devices touching intact skin of patients such as blood pressure cuff or patient-care surfaces such as patient bed cots or table, a low-level disinfection may be done (Category II).[17, 46-48,50-52,59-65]
3. *Monitoring of sterilisers:*
   a. Mechanical, chemical, and biologic monitors must be used to ensure the effectiveness of the sterilisation process (Category IB).[66-76]
   b. Each load has to be monitored with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators. External indicator is not needed, if the internal chemical indicator is visible (Category II).[66-84]
   c. If the device quality indicators (external or internal) in case of chemical or mechanical parameters suggest incomplete processing, then the batch should be rejected and redone (Category IB).[66-69,71]
   d. Biologic indicators should be used to monitor the effectiveness of sterilisers at least weekly with an FDA-approved commercial preparation of spores (e.g., *Geobacillus stearothermophilus* for steam) intended specifically for the type and cycle parameters of the steriliser (Category IB).[66,68-85]

   In use of biological indicators after a single positive indicator, if the process used is any other than a steam sterilisation, all the items are to be considered as non-sterile and thus should be again sent for re-sterilisation. This also draws attention to identification of all items in the batch or series that have been sterilised using the same biological indicator and the same method (Category II).[85]

   In case of use of a biological indicator for assessment of steam sterilisation and the result is seen as positive, then the item/device other than implantable devices does not require re-sterilisation unless it is determined that the positive result of the biological test agent is the result of defective maintenance. In case of steam sterilisation, if additional test results are found as positive, then the batch is considered to be unsterile and the alternative instrument or technique should be used (Category II).[85]

   Biological indicators are the preferred choice to be used with each batch particularly containing implantable devices and the test result should be negative till further use or declared safe for use (Category IB).[66-69,71]
4. *Storage of sterile items:*
   a. The area for storing the sterile equipment should be a well-ventilated area and must provide protection from excess humidity, moisture, pests, and dust (Category II).[2,71,85,86]
   b. Sterile items should be stored in such a way that the packaging is not compromised (e.g., punctured, bent) (Category II).[71,85-89]
   c. After completion of the sterilisation, all the items thus completed must be organised and labelled in a batch along with the date of processing, method used, and the expiration date or reuse by date (Category IB).[66-69,71,87]
   d. The adequacy of the sterility of a packed batch of item depends on multifactorial issues starting from the cover used, container quality, storage place conditions, and contamination that can happen in such areas (Category IB).[2,71,87-90,97]
   e. All packed items in a batch must be checked for marks of inadequate sterilisation as seen with damaged packets. If there are no adverse marks, then the pack may be used as such (Category II).[71,88]
   f. If the integrity of the packaging is compromised (e.g., torn, wet, or punctured), item should not be used and should be repacked and reprocessed the pack before use (Category II).[71,91]
   g. If time-related storage of sterile items is used, then pack should be labelled at the time of sterilisation with an expiration date. Once this date expires, the pack should be reprocessed (Category II).[71, 88]
5. *Quality control:*
   a. All staff assigned to reprocess semi-critical and critical medical/surgical instruments should have comprehensive intensive training to ensure that they understand the importance of reprocessing these instruments. The key to achieve and replicate the competent cycle, attention to details in implementation, and adequate training must be

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imparted to each participant of the team who are responsible for handling critical and semi-critical items. Written reprocessing instructions should be reviewed regularly to ensure that they comply with the scientific literature and the manufacturers' instructions (Category IB). [6-8,36,37,47,51,68,71,92]

b. Reprocessing instructions (e.g., for the appropriate use of endoscope connectors, the capping/non-capping of specific lumens) provided by the instrument manufacturer and the steriliser manufacturer should be compared and conflicting recommendations, if any, should be resolved by communicating with both manufacturers (Category IB).[36,37]
c. In areas of high risk of contamination and use of critical and semi-critical devices, infection control rounds with the aim to inspect, implement the sterilisation parameter must be checked and any deficiency thus identified must be promptly corrected (Category IB).[6-8,51]
d. The following should be included in a quality control program for sterilised items—a steriliser maintenance contract with records of service; a system of process monitoring; air-removal testing for pre-vacuum steam sterilisers; visual inspection of packaging materials; and traceability of load contents (Category II).[66-69,71]
e. For each sterilisation cycle, record the type of steriliser and cycle used; the exposure parameters (e.g., time and temperature); the load identification number and the load contents; the operator's name or initials; and the results of mechanical, chemical, and biological monitoring (Category II).[66-69,71]
f. The detailed record-keeping of the various modes of sterilisation methodology adapted should be retained as per local protocols (Category II, IC).[93]
g. Items to be sterilised are prepared and packed in a way so that sterility can be achieved and maintained to the point of use. Association for the Advancement of Medical Instrumentation or the manufacturers of surgical instruments, sterilisers, and container systems should be consulted for guidelines for the density of wrapped packages (Category II).[66-69,71]
h. Policies and procedures for sterilisation should be periodically reviewed (Category II).[93]
i. Timely and proper maintenance of sterilisation devices by trained staff in knowledge of the equipment and in compliance of the manufacturers' requirements to be performed at regular interval (Category II).[63]

STERILISATION OF LAPAROSCOPIC INSTRUMENTS

As laparoscopic instruments can be classified as 'critical' items according to Spaulding's classification, these instruments are required to be *sterilised* before being used in a surgical procedure.

The major methods used in the sterilisation of laparoscopic devices are as follows:

- Steam sterilisation
- *Chemical disinfection:*
  - Glutaraldehyde
  - H_2O_2
  - OPA
  - Per-acetic acid
  - Para-safe
- Ethylene oxide
- Newer methods—gas plasma sterilisation.

The sterilisation process of laparoscopic devices consists of six steps:

1. Cleaning is a very important step in the sterilisation/disinfection of endoscopes.
2. Rinsing and drainage of the channels present in the device/instrument.
3. Disinfection of the device/instrument.
4. Rinsing of the device/instrument with sterile water; If not possible/feasible, RO water can be used only if it is followed by an alcohol rinse.
5. Drying of the device/instrument.
6. Storage.

Steam Sterilisation

Steam sterilisation is achieved by saturated steam under pressure. It is cheap, easily available, non-toxic procedure and it can also penetrate fabric. Because of all its advantages, it is the method of choice for sterilisation of all items except those which are moisture or heat sensitive.

There are four major and important parameters in the process of steam sterilisation: (1) Steam, (2) Temperature, (3) Pressure, and (4) Time.

Caution:

- *To achieve sterilisation:* Air must be eliminated and steam must reach the item for the stipulated amount of time, at the stipulated temperature.
- Anhydrous materials (oil, greases, powders) can never be sterilised by steam because steam cannot penetrate such substances and collects on the outside of the object. The appropriate method for such materials is dry heat.

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- Hollow needles or instruments packed in moisture-resistant materials (test tube, glass) can never be penetrated by steam, and therefore steam sterilisation should not be used for those. If an instrument is kept inside a glass container for protection, it should not be tightly sealed but should be plugged with a loose cotton plug that can allow steam to go through. The container should be kept in such a position that air can easily be removed by steam (place sideways).
- Saturated steam (100% relative humidity) is best for sterilisation as it has a high heat content. Ideally, there should not be any water, not even in the form of a fine mist. If saturated steam has been used for sterilisation, at the end of cycle, the packed equipment should come out dry from the steriliser. Wet equipment packs are considered as non-sterile.
- Surgical dressings (hand towels, lap sheets, towels, table drapes, sponges, gowns) form a large bulk of the materials that need to be sterilised. These materials are kept and arranged in surgical packs. To obtain adequate sterilisation, surgical packs should not be more than 30 cm × 30 cm × 50 cm in size and an average weight of 5.5 kg.

Studies have shown that both the standard 10-minute cycle and the 3-minute 'flash' are uniformly successful in killing all pathogenic micro-organisms. A 7-minute steam sterilisation is necessary to kill spores within sealed cannulas. A standard 10-minute cycle within the steam autoclave provides complete sterilisation of laparoscopic instruments; the 3-minute 'flash' sterilisation is safe for instruments that have been unintentionally contaminated or dropped during a surgical procedure.[94]

Glutaraldehyde

Glutaraldehyde (Cidex® = 2% glutaraldehyde) is usually used as a HLD (30 minutes contact time). It can be used even as a chemical steriliser (10 hours contact time).

Activation and Shelf-life

A 2.5% solution is sold in the market that needs to be activated. Aqueous solutions are acidic and in this acidic pH range glutaraldehyde is not sporicidal. Once they are made into an alkaline solution (activated) at pH 7.5 to 8.5, they become sporicidal. But due to polymerisation that occurs at alkaline pH, the activated alkaline solution has a limited shelf-life of 14 days.

The minimum concentration to be effective is 1–1.5%. Checking of the concentration periodically is important as glutaraldehyde may get diluted in an automatic washer (concentration goes from 2.5% to 0.5% in 3 days). Formulations of glutaraldehyde are prepared with phenol/phenates to give it a longer shelf-life (up to 28 days).

Concentration/Time, Activity

It takes 2 minutes to kill vegetative bacteria, 10 minutes to kill fungi and hydrophilic viruses, and 3 hours for spores of *Bacillus* and *Clostridium*. *M. tuberculosis* is killed in 20 minutes but suspensions of atypical mycobacteria (*M. avium*, *M. gordonae*) are less sensitive and may take up to 30 minutes to be eliminated.

Advantages

- Non-corrosive in nature
- Active in presence of organic matter
- Works fine with lensed instruments, rubber, and plastics
- Coagulation of proteinaceous material does not take place.

Shortcomings

- It can cause irritation to healthcare workers exposed in poorly ventilated areas.
- Unstable; the activity needs to be monitored closely. Leaves some residue on metals and endoscopes.

Uses/Misuses

It is a type of cold steriliser for items that are heat-sensitive which cannot be autoclaved or gas sterilised—endoscopes, respiratory therapy equipment, spirometry tubing, anaesthesia, transducers, and dialysate delivery systems.

Several studies have documented that ≥2% aqueous solutions of glutaraldehyde, buffered to pH 7.5–8.5 with sodium bicarbonate, takes <2 minutes to eliminate vegetative bacteria; <10 minutes for *M. tuberculosis*, fungi, and viruses; and 3 hours for spores of *Bacillus* and *Clostridium* species.[95,96]

Hydrogen Peroxide

Hydrogen peroxide (H_2O_2) is available in the market as a 3% solution or as a 30% stabilised solution. A 6% solution can also be used for disinfection—it is prepared just before use, mixing the 30% stabilised solution and sterile water in 1:4 ratio.

It takes several hours to eliminate spores but takes <1 hour to kill all other microbial forms.

Shortcomings

- 30% concentrate is corrosive in nature. It should be stored in a cool and dry place away from sunlight.
- It is corrosive to metals.

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Uses

- It is used as a surface disinfectant.
- It is used for the disinfection of contact lenses used in refractive errors.
- It is used for disinfection of ventilators.

Studies have documented that H_2O_2 sterilisation is more potent in achieving microbiological safety. When treated with H_2O_2 gas sterilisation, laparoscopic instruments can confidently be reused without increased risk of infection to the patient.[97]

Peracetic Acid

Peracetic acid solutions are stabilised solutions of per-acetic acid, H_2O_2, and acetic acid.

Concentration/Time, Activity

Peracetic acid solution is sporicidal in low concentrations (100–2000 ppm). It eliminates vegetative forms within 5 minutes at 100 ppm, within 5 minutes at 500 ppm in presence of organic matter, kills all viruses within 15 minutes at 2200 ppm, inactivates spores within 15 seconds at 10,000 ppm (1%), or within 15 minutes at 500 ppm.

Advantages

- It is rapid in action.
- No harmful decomposition products are produced.
- No residue is left.
- It is effective even in presence of organic matter.

Shortcomings

- Corrosive for metals
- Chemically unstable—a 1% solution loses its strength within 6 days.

Uses/Misuses

- Automated machines are in use, using peracetic acid to sterilise medical, surgical, and dental equipment.
- It is used in reprocessing of dialysers.

Presently in the US, two variants of peracetic acid solutions have been approved by the FDA for use as sterilants or HLDs. One is manufactured for single use in an automated system (Steris®). The second solution is sold pre-diluted and ready to use.

Unlike the more concentrated solutions, this ready-to-use solution is not a skin irritant, though it is corrosive to ocular tissue.

Three clinical trials have shown the microbiocidal property of per-acetic acid without any clinical failure that might lead to infection.[98-101]

Ethylene Oxide Sterilisation

Ethylene oxide is used almost exclusively to sterilise heat-sensitive medical products that cannot be sterilised by steam. ETO is a colourless gas with inflammable and explosive properties; however, mixtures of ETO (10–12%) with carbon dioxide or the fluoridated hydrocarbons are less inflammable. Because of its ill effect on the ozone layer, restrictions are increasingly being imposed.

The effectiveness of ETO sterilisation is determined by four essential factors:

1. *Temperature*: 29–65°C
2. *Gas concentration*: 450–1200 mg/L
3. *Exposure time*: 2–5 hours
4. *Humidity*: 45–85%

Activity: ETO inactivates all micro-organisms except the bacterial spores (especially *B. subtilis*) as they are found to be more resistant than other micro-organisms. That is why *B. subtilis* is used as a biologic indicator. ETO exerts its microbiocidal activity by alkylation of protein, DNA, and RNA. Within cells, replacement of a hydrogen atom with an alkyl group impedes normal cellular metabolism and replication.

Cycle time: 285 minutes + aeration time of 8–12 hours at 50–60°C.

Advantages: Heat- or moisture-sensitive medical equipment can be sterilised without any effect on them.

Plastic trocars subjected to high-level disinfection with ETO has been shown to be reused safely without infection risk and also with cost reduction.[102]

Disadvantages: Lengthy cycle time, higher costs, and its potential hazards to patients and healthcare workers.[103]

Precautions while use of ETO:

- Unload the steriliser immediately after each cycle, the door is to be opened only 5–10 cm and the healthcare worker should vacate the area for 15 minutes (unless the steriliser has a purge system that forces the gas out of the chamber).
- Exhaust directly to the outside.
- Room ventilation—10 air exchanges/hour, 50% relative humidity, and temperature = 21°C.
- ETO tanks should be kept upright and tightly, and securely fastened. If more than 10 kg is to be stored, the area should be made suitable for inflammable liquids.
- There should be an action plan for leaks and spills.

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Symptoms Associated with ETO Exposure

- Irritation of eyes, upper respiratory passages.
- Altered 'taste'.
- Headache, nausea, vomiting.
- Respiratory distress, cyanosis, pulmonary oedema, unsteadiness, and EKG abnormalities.
- Skin irritation, or burns if direct contact.
- Elevated lymphocytes, decreased Hb.
- High number of chromosomal aberrations.

Hydrogen Peroxide Plasma Sterilisation (Sterrad®)

This system uses an advanced technology—gas plasma is created in the electric field when radiofrequency emissions are applied to H_2O_2. A deep vacuum is then created to avoid using excessive heat and also to enable maximum dispersion of the H_2O_2 vapour around the equipment.[104] It is not known to produce any harmful substances; water and oxygen are the end products.

The Sterrad system is also fully automated and has a cycle time of 75 minutes:

- Vacuum stage taking up to 5–20 minutes reaching 0.3 torr
- Injection phase of 58% solution of H_2O_2 for 6 minutes
- Plasma stage during which the radiofrequency emissions are applied
- Air-flush stage (2 minutes) made up of a series of vacuum and re-pressurisations with air filtered (0.03 μ filter).

Shortcomings

- Any material that absorbs liquids such as cellulose (paper), linens, etc. cannot be processed.
- Items must be thoroughly cleaned and dried before going into the chamber.
- Moisture interferes with the capability to achieve a good vacuum.
- The sterilisation chamber is small.
- Expensive.

CONCLUSION

Along with the progress and rising popularity of laparoscopic procedures, sterilisation and disinfection of laparoscopic instruments become all the more important for better post-operative outcomes and to reduce post-operative complications such as surgical site infections.[105] Adherence to sterilisation and disinfection protocols with respect to time of exposure, pressure, temperature, etc. will ensure adequate microbiological safety of these instruments which in turn will help in better outcomes of laparoscopic procedures.

Authors' recommendations for safe use of laparoscopic instruments.

Laparoscopic instruments	*Autoclave/ flash autoclave*	*2% Glutaraldehyde*	*Parasafe*	*ETO*	*Gas plasma*	*Formalin chamber*	*Sterile sleeve*
Camera	×	++	++		+++	+	++
Light cable	+	++	++	+++	+++	+	++
Telescope	+++	++	++		+++	×	×
Tubings/ diathermy cables	×	+	+	+++	+++	+	×
Harmonic scalpel cable	×	++	++	+++	+++	+	++
Heat-sensitive hand instruments	×	++	++	+++	+++	×	×
Heat-resistant hand instruments	+++	++	++	+++	+++	×	×
Trocars	+++	++	++	+++	+++	×	×

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