

Sterilization is the process by which surgical items are rendered free of viable microorganisms, including spores. The purpose of effective laparoscopic instrument sterilization is to provide the surgeon with a sterile product.

## ■ HISTORY

According to ancient writings, most primitive people regarded disease as the work of evil spirits or as coming from supernatural powers. Hippocrates (460–370 BC) began the shift of the healing process from mystical rites to a practical approach. Marcus Terentius Varro (117–26 BC) proposed a germ theory by stating, “Small creatures, invisible to the eye, fill the atmosphere, and breathed through the nose cause dangerous diseases.” Seventeenth century advancements in anatomy, physiology, and medical instrumentation included the development of the microscope in 1683 by Antonie van Leeuwenhoek which allowed bacteria to be studied. Research into surgery and anatomy continued during the eighteenth century. In the 1850s, Pasteur proved that fermentation, putrefaction, infection, and souring are caused by the growth of microbes. Lord Joseph Lister was the one who successfully identified the implications for surgical infections. Lister believed that infection could be prevented if he could prevent the airborne microbes from entering the wound. Further advances in aseptic techniques from 1881 to 1882 were possible when a German bacteriologist, Robert Koch, introduced methods of steam sterilization and developed the first nonpressure flowing steam sterilizer.

## ■ LEGISLATION IN STERILIZATION

The sterilization of laparoscopic instruments must comply with safety standards. These vary depending upon legislation of the individual countries.

In Germany, legislation requires steam autoclaving at 134°C for 5 minutes. However, in France, sterilization is practiced at this temperature for 18 minutes. In the United States of America, Food and Drug Administration (FDA) has established different sterilization criteria regarding sterilization of reusable instruments. General requirement for characterization of sterilizing agent and the development, validation and routine control of a sterilization process for laparoscopic instrument is provided by the manufacturer

and sterilization should be performed strictly according to the manufacturer’s guidelines.

## Cleaning

All used instruments, regardless of size, should be completely immersed in distilled water before leaving the operating room. The first step of the high-level disinfection process is thorough cleaning (Fig. 1). Cleaning removes debris, mucus, blood, and tissue (bioburden) which would interfere with the action of the disinfectant. Current recommendations specify disassembly of most laparoscopic equipment prior to sterilization. If the surgical assistants are unfamiliar with the proper assembly of laparoscopic instruments, it may cause patient injury from equipment malfunction. Because of the intricate internal parts of laparoscopic instruments, questions have been raised about the efficacy of cleaning and sterilization techniques.

In the instruments which cannot be dismantled, there is separate channel to irrigate water under pressure to clean it properly. At least 300 mL of water should be flushed through these instruments to clean it properly.

Approximately 99.8% of the bioburden can be removed by meticulous cleaning. Cleaning may be accomplished via manual or mechanical washing or enzyme detergent application (Figs. 2 and 3).

## Ultrasonic Technology for Cleaning

- Energy from high-frequency sound waves
- Vigorous microscopic implosions of tiny vapor bubbles
- Millions of scrubbing bubbles do the job of cleaning
- Ultrasonic cleaners facilitate removal of organic material, decreasing the risk of contaminants.

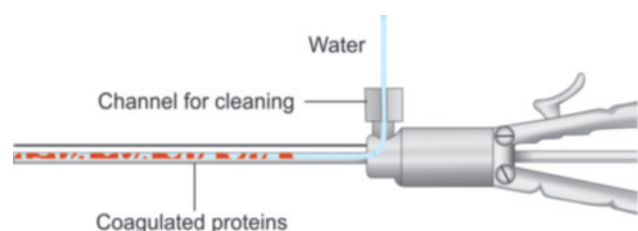


Fig. 1: Incomplete cleaning can result in accumulation of coagulated protein inside channel of the instrument.



Fig. 2: Enzyme-based laparoscopic instrument cleaner.

The cleaning agent selected should be:

- Able to remove organic and inorganic soil
- Able to prevent waterborne deposits
- Low foaming
- Able to be rinsed completely
- Compatible with the materials being cleaned.

### Enzymatic Laparoscopic Instrument Cleaner

The enzyme-based laparoscopic instrument cleaner has been shown in **Figure 2**.

Enzyme-based cleaner has an enzymatic detergent solution. The solution gets into hard-to-reach parts of your equipment for thorough cleaning. The enzymatic cleaning detergent has the following advantages.

- Increased activity on proteins (like blood, feces, and mucous) with protease enzyme.
- Advanced formulation quickly and thoroughly penetrates organic matter
- The safe, biodegradable base is easy on you and the environment.

Following cleaning, items to be disinfected must be rinsed thoroughly to remove any residual detergent. After cleaning, instruments are subjected to sterilization.

### Sterilization

The two methods of sterilization most commonly used for laparoscopic instruments are:

1. Steam sterilization
2. Chemical sterilization

Autoclaving by means of steam was the oldest, safest and most cost-effective method of sterilization. When steam is placed under pressure and the temperature is raised, the moist heat produces changes within the cell protein, thereby rendering it harmless over a prescribed period of time. The relationship between temperature, pressure and time of



Fig. 3: Ultrasonic laparoscopic instrument cleaner.

exposure is the critical factor in the destruction of microbes. Although steam sterilization is effective and inexpensive it is not suitable for all laparoscopic instruments.

The growth and expansion of minimal access surgical procedures require specialized surgical instrumentation. Most of the laparoscopic instrument can be safely autoclaved but some of the laparoscopic instruments cannot withstand the prolonged heat and moisture of the steam sterilization process. Laparoscopic cameras, laparoscopes, light cables, and flexible endoscopes are damaged by heat. Therefore, alternative methods of sterilization were needed to effectively sterilize moisture-stable, moisture-sensitive, and heat-sensitive items that require rapid, frequent processing in the clinical setting.

One of the most common types of alternative of steam sterilization is chemical sterilization. Many chemicals are proven to have sterilizing property. Laparoscopic camera [charge-coupled device (CCD)] is damaged by chemical sterilization with repeated exposure. In these expensive devices, a sterile plastic sleeve or sterile thick cloth sleeve should be used to avoid contamination.

### Ethylene Oxide

One of the most common types of chemical sterilization uses ethylene oxide (EtO) gas, which is in use since the 1950s. EtO is colorless at ordinary temperatures, has an odor similar to that of ether and is extremely toxic and flammable. Mixture of EtO with an inert gas such as carbon dioxide or a chlorofluorocarbon (CFC) was used to make it nonflammable. The most common combination was 12% EtO and 88% freon. A newer formulation uses EtO plus a hydrochlorofluorocarbon (HCFC).

Ethylene oxide sterilization depends on four parameters:

1. Time
2. Temperature

3. Gas concentration
4. Relative humidity

All EtO sterilizers operate at low temperature, typically between 49 and 60°C (130–140°F) and relative humidity of 40–60%. The humidity must be not <30% in order to hydrate the items during the sterilization process. These characteristics make EtO sterilization suitable for complex medical equipment.

Both temperature and humidity have a profound influence on the destruction of microorganisms because they affect penetration of the gas through bacterial cell walls, as well as through the wrapping and packaging materials. It typically takes between 3 and 6 hours for the sterilization portion of the cycle to be completed.

Additionally, items sterilized by EtO must be aerated to make them safe for personnel handling and patient use. The main disadvantages associated with EtO are the lengthy cycle time, the cost, and its potential hazards to patients and staff; the main advantage is that it can sterilize heat- or moisture-sensitive medical equipment without deleterious effects on the material used in the laparoscopic devices. Therefore, the EtO sterilization and aeration processes can take up to 20 hours and should be used only when time is not a factor.

### Hydrogen Peroxide Gas Plasma

Hydrogen peroxide is an oxidizing agent that affects sterilization by oxidation of key cellular components. Gas plasmas have been referred to as the fourth state of matter (i.e., liquids, solids, gases, and gas plasmas). The cloud of plasma is composed of ions, electrons, and neutral atomic particles that produce a visible glow. Hydrogen peroxide is bactericidal, virucidal, sporicidal, and fungicidal, even at low concentration and temperature. Gas plasmas are generated in an enclosed chamber under deep vacuum using radio-frequency or microwave energy to excite the gas molecules and produce charged particles, many of which are in the form of free radicals. A free radical is an atom with an unpaired electron and is a highly reactive species. The mechanism of action of this device is the production of free radicals within a plasma field that are capable of interacting with essential cell components (e.g., enzymes, nucleic acids) and thereby disrupt the metabolism of microorganisms. The type of seed gas used, and the depth of the vacuum are two important variables that can determine the effectiveness of this process.

A solution of hydrogen peroxide and water (59% nominal peroxide by weight) is vaporized and allowed to surround and interact with the devices to be sterilized. Applying a strong electrical field then creates plasma. The plasma breaks down the peroxide into a “cloud” of highly energized species that recombine, turning the hydrogen peroxide into water and oxygen. No aeration time is required and the instruments may either be used immediately or placed on



Fig. 4: Hydrogen peroxide gas plasma.

a shelf for later use. A load of surgical instruments may be sterilized in <1 hour (Fig. 4).

A newer version of the unit improves sterilizer efficacy by using two cycles with a hydrogen peroxide diffusion stage and a plasma stage per sterilization cycle. This revision, which is achieved by a software modification, reduces total processing time from 60 to 30 minutes. Laparoscopic instruments that cannot tolerate high temperatures and humidity of autoclaving, such as some hand instruments, electrical devices, and corrosion-susceptible metal alloys, can be sterilized by hydrogen peroxide gas plasma very efficiently. This method has been compatible with most (>95%) laparoscopic instruments.

### Peracetic Acid

Liquid peroxyacetic acid, or peracetic acid, is a biocidal oxidizer that maintains its efficacy in the presence of high levels of organic debris. Peracetic acid is acetic acid plus an extra oxygen atom and reacts with most cellular components to cause cell death. The peracetic acid solution is heated to 50–56°C (122–131°F) during the 20–30 minutes cycle. Peracetic acid must be used in combination with anticorrosive additives.

Parameters for peracetic acid sterilizers include:

- Relatively short cycle times
- Availability of the items for immediate use
- Sterilant can be discharged into the drainage system since it is not hazardous
- No aeration time is required for the sterilized items
- Items must be rinsed with copious amounts of sterile water after the sterilization process.

Items processed by this method should be used immediately after processing, since the containers are wet and are not protected from the environment. This system must also be monitored for sterility with live spores.

## Glutaraldehyde

An activated 2% aqueous glutaraldehyde solution is recognized as an effective liquid chemical sterilant. Glutaraldehyde is most frequently used as a high-level disinfectant for lensed instruments because it is non-corrosive and has minimal harmful effect on the instrument (Fig. 5).

Sterilization can be achieved with an activated 2% glutaraldehyde solution after the item is completely immersed for 10 hours at 25°C in especially designed tray. Before immersion, the item must be thoroughly cleaned and dried. During immersion, all surfaces of the item must be in contact with the solution. After immersion, the item must be rinsed thoroughly with sterile water prior to use (Fig. 6).

Cidex should be used maximum 15 times or 21 days after activation, whichever may be earlier. Once activated, the solution should be discarded after 21 days, so it is important to write the date of activation and date of expiry in the space provided on the Cidex tray (Fig. 7). If the instrument is not

cleaned properly, the activated glutaraldehyde becomes dirty just after few use and turns into blackish solution. In this case, it should be rejected before specified period of time. It is important that surgeon should read carefully the literature provided by the manufacturer.

## Ortho-phthalaldehyde

For laparoscopic instruments, 0.55% ortho-phthalaldehyde (OPA) is good option, it is nonglutaraldehyde solution for disinfection of delicate instruments. In fact, OPA solution is one of the gentlest reprocessing options available, which means it can substantially reduce instrument damage and repair costs. OPA solution offers excellent materials compatibility and can therefore be used to disinfect a wide range of medical instruments made of aluminum, brass, copper, stainless steel, plastics, elastomers. It is good not only because of its speed and efficiency but also because of its environmental safety. It comes with the trade name of Cidex OPA (Fig. 8).



Fig. 5: Cidex (2% glutaraldehyde).



Fig. 6: Cidex tray used for laparoscopic instrument sterilization.

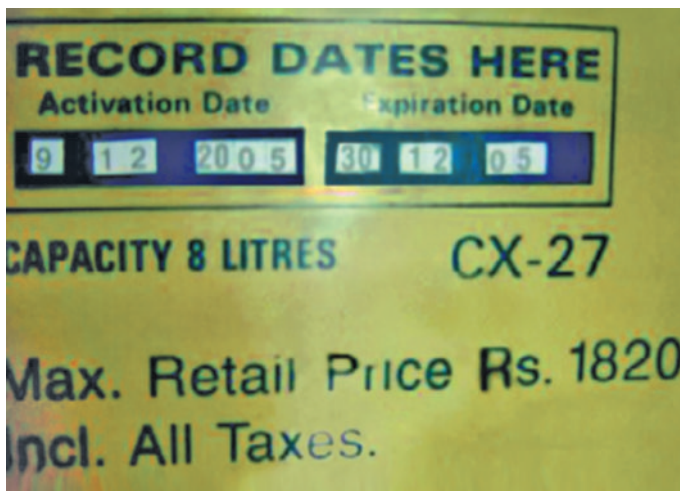


Fig. 7: Labeling of Cidex tray (activation date and expiration date).



Fig. 8: Cidex<sup>®</sup> ortho-phthalaldehyde (OPA) high-level disinfectant.

It has following advantages:

- No activation or mixing required
- It can be used in both automated and manual reprocessing
- Two years shelf-life and 75 days open-bottle shelf-life
- Rapid 5 minutes immersion time at a minimum of 25°C in an automatic endoscope reprocessor
- Efficient 12 minutes soak time at room temperature (20°C) for manual reprocessing
- Effective against glutaraldehyde-resistant *Mycobacterium*.

## Formaldehyde

Bactericidal properties and use of formaldehyde include: 37% aqueous solution (formalin) or 8% formaldehyde in 70% isopropyl alcohol kills microorganisms by coagulating intracellular protein. Solution is effective at room temperature.

Specially designed airtight formalin chambers are available (**Fig. 9**). Eight to ten formalin tablets wrapped with moist gauze piece should be placed in the chamber and the door should be closed. The vapor of formalin acts for 1 week, after 1 week, tablets should be changed. Although known to destroy spores, it is rarely used because it takes from 12 to 24 hours to be effective. Formalin chamber is used by many surgeons to carry their sterilized instrument from one hospital to another. Pungent odor of formalin is quite objectionable and irritating to the eyes and nasal passages. The vapors can be toxic and ongoing controversy exists regarding its carcinogenic effects.

## Other Chemical Disinfectant

Recently, nonaldehyde instrument disinfectant is available for rapid decontamination of noninvasive and heat labile laparoscopic instruments. It contains halogenated tertiary amines, polyhexamethylene biguanide hydrochloride,

ethyl alcohol B, dodecylamine, and sulfamic acid. Contact time for bactericidal, fungicidal, and virucidal protection is 10 minutes. For sporicidal protection, contact time is 30 minutes.

## CONCLUSION

Most of the laparoscopic instrument can be easily sterilized if the person knows how to disassemble, clean and use specific chemical for sterilization. Manufacturer's instruction is important to follow if desired effect has to be achieved. Expensive instruments should be handled carefully and all the insulated instruments should be checked thoroughly for any breach in insulation before sterilization. Apart from newer generation chemical disinfectant, low-temperature steam with formaldehyde has been widely used in healthcare facilities in Northern Europe for the sterilization of reusable medical devices that cannot withstand steam sterilization.

Other key considerations in the sterilization process which should be taken care are:

- Packaging of the items after sterilization
- Monitoring the sterilization process
- Shelf life of the sterilized items
- Cost implications

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Fig. 9: Formalin chamber.

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## Contact us

 World Laparoscopy Hospital  
Cyber City, Gurugram, NCR Delhi  
INDIA : +919811416838

 World Laparoscopy Training Institute  
Bld.No: 27, DHCC, Dubai  
UAE : +971523961806

 World Laparoscopy Training Institute  
8320 Inv Dr, Tallahassee, Florida  
USA : +1 321 250 7653