Sterilization and Disinfection

Chris Gross, Sanaz Dovell

INTRODUCTION:

This chapter will cover the topics of decontamination, disinfection, and sterilization of medical items, instruments and equipment. Due to its broad (and non-sequential) nature, we will break this chapter into four major parts: terms, theory, tools/techniques and practices. Our hope is that this overview will set a foundation for understanding the basics of decontamination, disinfection and sterilization. Note there is intentional redundancy within this chapter, as with other chapters within the Manual itself.

Scope of problem:

1. Safe surgery requires a sterile procedure to minimize life-threatening infections. Sterile procedures require sterile instruments.
2. Global access to safe surgery is limited by a lack of access to sterilization.
3. Resource-constrained settings may not have reliable access to reliable electricity, making the use of the autoclave, the WHO standard for sterilization, difficult or impossible.
4. Staff responsible for cleaning and sterilizing the surgical equipment may have limited training in sterile processing techniques.

Impact of problem:

1. Approximately five billion people around the world do not have access to much-needed surgical care, and as much as 33% of worldwide deaths are from surgically treatable conditions.
2. Lack of proper instrument sterilization has led to post-surgical infection rates as high as 46%.
3. Disposable kits, often thought of as a fix to the problem, are not a viable solution because they generate large amounts of biowaste that is difficult to properly dispose of in low-resource areas.

TERMS:

1. **Cleaning** is defined as removing any visible soil. Cleaning is typically achieved by manually combining water with enzymes or detergents and using a brush to physically remove visible debris. It is important to note that *clean* does not mean *sterile* or *disinfected*.
2. **Decontamination** is defined as removing pathogenic organisms in order to make objects safe enough to handle, use, or dispose of.
3. **Disinfection** is the process of eliminating *most* pathogenic organisms with the exception of spores. This is usually accomplished with liquid chemicals or wet pasteurization.
4. **High-level disinfection** is defined as the complete elimination of all microorganisms in or on an instrument, with the exception of a small number of bacterial spores.
5. **Intermediate-level disinfection** is the elimination of all microorganisms, but not spores.
6. **Low-level disinfection** kills fungi, most bacteria, some viruses, and no spores.
7. **Sterilization** is the process of eliminating all microorganisms, and is commonly achieved through chemical and/or physical means.
8. **Germicide** is an agent that can eliminate microorganisms. Agents with 'cide/cidal' suffixes have some type of killing action that is referenced in the name (i.e fungi-cide). Note that **germicides** include both **antiseptics** and **disinfectants** (remember disinfectant differs from disinfection).
    a. **Antiseptic** germicides are agents that can be applied to living tissue (i.e skin).
    b. **Disinfectant** is any germicide agent that can be applied to non-living tissue (i.e. not skin). It is *only* used to disinfect surfaces of inanimate objects because of the risk of injury to tissue.
9. **Critical items** are any items with a high chance of transmitting an infection if that instrument/item becomes contaminated (surgical instruments, urinary catheters, implants). These items must be completely sterile.
10. **Semi-critical items** are any items/instruments that come into contact with non-intact skin and/or mucous membranes (respiratory / anesthesia equipment). These items should undergo cleaning, followed by high-level disinfection.

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11. **Non-critical items** are any items/instruments that come in contact with intact skin and do not come in contact with mucous membranes (bedpans, computers, patient furniture). It is not critical for these items to be sterile as long as they do not come in contact with non-intact skin or mucous membranes.

THEORY:

Before diving into the individual techniques for achieving sterility, it is important to discuss the factors that influence our ability to get an item clean, decontaminated, disinfected, and/or sterilized. We will divide these factors into those that are internal to the offending organism and factors that are external to the offending organism.

Factors internal to the organism

Organism type: The first major internal factor is the type of microorganism(s) present on the object and whether or not spores are involved. The major types of organisms to consider for disinfection, listed in order of most-to-least difficult to eradicate, are prions, bacterial spores, mycobacteria, non-lipid viruses, fungi, bacteria, and lipid viruses. Each type of organism has a varying level of susceptibility to destruction, which is related to its physical structure (i.e lipid envelope or protein capsid). For example, spores are generally resistant to most disinfectants while mycobacteria are generally resistant to alcohol, and prions are resistant to heat at 200 ºC for as long as two hours.

Organism quantity: Just as microbes grow at an exponential rate, microbes also die at an exponential rate. As the number of organisms increases, a longer exposure time is required to achieve disinfection or sterility. Proper cleaning with water and detergent or enzymatic cleansers prior to disinfection or sterilization can help to reduce the microbial load and increase the effectiveness of the disinfectant or sterilant.

Most bacteria create a biofilm on solid organic or inorganic surfaces when the number of organisms reaches a certain level. The biofilms contain an extracellular matrix of proteins and polysaccharides that encourage binding of more bacteria both to the matrix and to each other, providing stability, nutrition, and protection. Biofilms are known to significantly decrease the effectiveness of antimicrobial agents through different adaptations that shield one another from the toxic effects of the disinfectant, slow disinfectant penetration, and even prevent antimicrobial agents from reaching bacteria at the center of the biofilm, all of which prevent sterility from being achieved.

Factors external to the organism

Surface factors: Smooth surfaces are easier to disinfect while objects with rough surfaces are more difficult because of the microscopic crevices that can house microorganisms. In addition, the organic load – the presence of organic material like blood or tissue – inhibits the action of disinfectants. A high organic load can block neutralizing agents from reaching the surface, and biomaterial itself can even inactivate agents such as bleach. Proper cleaning with water and detergent or enzymatic cleaners prior to disinfection or sterilization can reduce the organic load and increase the effectiveness of the disinfectant or sterilant. Similarly, biofilms created by certain organisms prevent agent contact with the organism itself, thereby requiring both a longer contact time overall, as well as higher agent concentration.

Agent factors: The **concentration** of the disinfecting agent is an important factor to consider when attempting disinfection or sterilization, as higher concentrations of a chemical agent do *NOT* always increase the microbial death rate. For example, a 70% isopropyl alcohol solution can kill microorganisms in seconds because water both allows the isopropyl alcohol to enter and penetrate the entire cell and increases the contact time of the disinfectant on the surface by slowing the rate of evaporation of the isopropyl alcohol. Conversely, solutions with concentrations above 91% are not as effective because the alcohol's action on the outer layer of microbes creates a protective layer of denatured proteins, which actually shields other proteins from becoming denatured. Lastly, no concentration of isopropyl alcohol effectively kills

spores, thus alcohol cannot be used to achieve high-level disinfection or sterilization.

Duration of exposure: **Time** is also important. The time required for disinfection is a function of bacterial load, concentration of the disinfecting agent, as well as intrinsic properties of the disinfecting agent. For example, 70% isopropyl alcohol can kill Mycobacterium tuberculosis in 5 minutes, whereas a 3% solution of phenol requires 2-3 hours to achieve the same effect.

The efficacy of disinfecting and sterilizing agents is described by their decimal reduction time (D-value), or death rate curve, which is the amount of time it takes to kill 90% of the microbial population. For example, an antimicrobial agent with a D-value of one minute will kill 90 million cells in a population of 100 million bacterial cells, leaving 10 million cells alive after one minute. However, after two minutes, one million bacterial cells will still be alive because this agent is known to kill 90% of the bacterial cells in one minute. Therefore, sterilization, which requires eradication of all living cells, viruses, and spores, can be achieved by certain agents by increasing the duration of sterilization to several D-values longer than the time needed to theoretically reduce the microbial population down to one cell. For example, glutaraldehyde-based solutions of ~2% can achieve high-level disinfection (elimination of microorganisms but not spores) with exposure times of 12-30 minutes, but sterilization can be achieved with an exposure time of 10 hours. Proper protocols, including concentration and exposure time, should be carefully considered and adhered to when selecting the appropriate agent for disinfection or sterilization.

Physical factors: In general, most disinfectants work at room temperature (~20-22C), and, to some extent, the temperature is directly proportional to the activity of the disinfectant. Certain disinfectants require a specific pH to be active, while others cannot be used together because they can neutralize one another. Additionally, an agent's physical properties must be taken into account. For an antimicrobial agent to effectively kill microbes at the concentration and amount of time determined by studies, the agent must remain in contact with the item being disinfected for the entire duration of time. For example, while 70% isopropyl alcohol may kill *M. tuberculosis* in 5 minutes, if the 70% isopropyl alcohol being used evaporates within 30-60 seconds, then disinfection will not be achieved.

TOOLS AND TECHNIQUES

As mentioned above, both the instrument type and organism type must be considered when determining the best method for sterilization. Broadly, the techniques can be divided into physical methods (heat) and chemical methods. In all situations, the instruments must be disassembled as much as possible and thoroughly cleaned with water and detergent or enzymatic cleaners to remove all foreign material from the surface of the equipment. Failure to do so can significantly limit the effectiveness of the sterilization process.

Physical methods:

The primary physical methods include applications of dry heat and moist heat, with moist heat being more effective due to water's ability to penetrate the cells.

Dry heat: Dry heat is used for sterilizing metal objects, powders and glassware (all other materials will melt). It requires both higher temperature (160 to 180 ^{o}C) and longer exposure time (1-3 hours) than moist heat. Ovens are very common in dental offices, and due to their simplicity, they can be used in resource-constrained settings.

Electric heat sterilizer in a dentist's office

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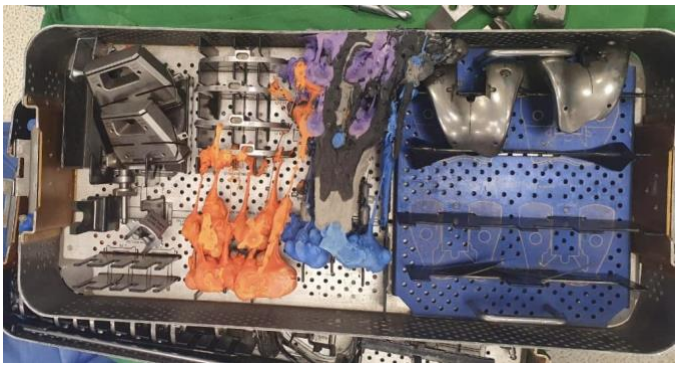
Moist heat: Moist heat at high pressure, also known as steam sterilization, is the simplest and most frequently used method of heat sterilization. Moist heat alone (boiling water at 100 °C) can effectively kill most organisms, but spores easily survive. The use of moist heat at high pressure raises the boiling point of water to produce steam at a temperature that can effectively kill spores and achieve sterilization. Both pressure cookers and autoclaves use heat under the pressure of steam to eliminate organisms. Unlike dry heat, some hard plastics can be safely sterilized in this manner, such as orthopedic implants or some laparoscopic equipment.

Steam sterilization has four parameters: steam, pressure, temperature, and time. Standard sterilization procedures use steam at 121 °C (250 °F) at 15 psi (pounds per square inch) for 20-30 minutes, which effectively kills all spores to achieve sterility in a gravity displacement autoclave. At higher temperatures of 134 °C (273 °F), sterilization can be achieved in four minutes, if a pre-vacuum autoclave is used. Note that instruments packaged in kits with multiple layers, as well as liquids, require longer times in the autoclave.

Type of Sterilizer	Item	Exposure time at 121°C (250°F)	Exposure time at 132°C (270°F)	Drying time
Gravity displacement	Wrapped instruments	30 min	15 min	15-30 min
Gravity displacement	Textile packs	30 min	25 min	15 min
Gravity displacement	Wrapped utensils	30 min	15 min	15-30 min
Prevacuum	Wrapped instruments	N/A	4 min	20-30 min
Prevacuum	Textile packs	N/A	4 min	5-20 min
Prevacuum	Wrapped utensils	N/A	4 min	20 min

Minimum cycle times for steam sterilization; adapted from CDC (reference at end of Chapter.)



If the release valve fails, the autoclave can be turned into a dry heat autoclave, which creates higher temperatures and will likely melt any plastics in the device (in this case sizers for a knee arthroplasty set.).

Flash sterilization is a modification of the standard steam sterilization that sterilizes unwrapped items at 132 ºC for 3-4 minutes at 27-28 psi. It is designed for use only in emergency situations, when there is not enough time for a standard sterilization cycle. Items to be sterilized must have already gone through the proper cleaning and decontamination process. Since items are unwrapped, contamination can occur as soon as the item is removed from the sterilizer, increasing the risk of infection. Flash sterilization should be avoided for any implantable devices, and it should not be used as a method for convenience.

Filtration: Filtration can be useful if an IV medication used during a procedure must be sterilized, since heat or chemical sterilization will denature drug compounds. Micropore filters with pore sizes of 0.2 µm will remove bacterial cells, but not viruses. Filtration of viruses requires a pore size of 20 nm.

Irradiation: Ultraviolet radiation has poor penetration, therefore, it can only be used to sterilize surfaces. Other forms of ionizing radiation, such as gamma rays, are associated with higher costs and harmful effects on equipment compared to other methods of sterilization. Therefore, sterilization via irradiation is not recommended.

Chemical methods:

The most common chemical methods are iodine, alcohols, chlorine derivatives, glutaraldehyde, hydrogen peroxide, peracetic acid, enzyme solutions, and ethylene oxide. Not all chemicals can be used for sterilization, even with increased exposure time, and careful consideration of proper storage and disposal of these chemicals must be taken when selecting the appropriate agent to use.

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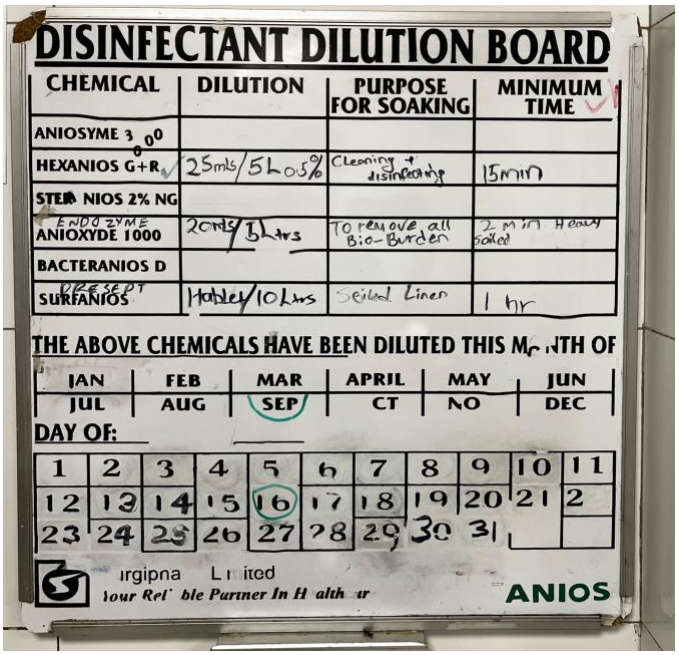


The chemicals in use can be tracked and standardized using an erasable board such as this one, supplied by the manufacturer of the chemicals.

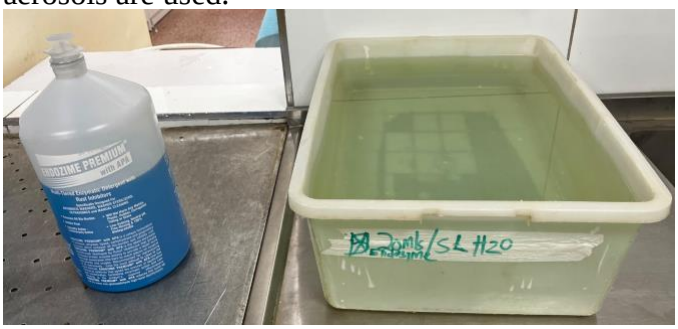
<u>*Iodine:*</u> Iodine often comes in the form of a tincture mixed with an alcohol or as an iodophor (iodine mixed with a solubilizing agent). Iodophors, which increase the activity of iodine, are found in ointments, surgical scrubs, and solutions such as Betadine (povidone-iodine). For iodine to become effective, it must be properly diluted (~ 10% solution), and have at least 30 seconds of contact time with the object. It is important to note that iodine is *not* sporicidal.

<u>*Alcohols:*</u> Isopropyl and ethyl alcohols are the most common type of alcohol used for low-level disinfection, but not sterility. Instruments are first thoroughly cleaned by scrubbing with water and detergent or enzymatic cleaner, then typically submerged overnight in 70% solution (ranges from 60-90%). These agents work well against most gram negative and gram positive bacteria, and are a common option in severely resource-limited settings. It is important to note that these alcohol agents are *not* sporicidal and are ineffective against hydrophilic viruses such as polio.

<u>*Chlorine*</u>: Chlorine and its derivative compounds are halogens that are commonly used for disinfection, as it can kill all microbes but cannot kill spores. The most common chlorine disinfectant is sodium hypochlorite (Chlorox, or bleach) which has a 1:10 dilution of 5.25% concentration (0.5% to 1% is required for disinfection). As mentioned previously, organic matter can inactivate bleach, so proper cleaning to remove biomaterial prior to the use of bleach is essential for proper disinfection.

Left: sodium percarbonate, tetraacetyl- ethylenediamine and N-alkyl(C12-14)-N-benzyl-N, N-dimethylammonium chloride tablets. Right: Didecylmethylammonium Chloride and Chlorhexidine Gluconate solution.

<u>*Enzymatic solutions*</u>: Enzymatic solutions use various proteases to break down biomaterial at neutral pH. They are used after initial washing and scrubbing, and can reduce organic load in difficult to reach areas of equipment without destroying delicate and expensive equipment. For this reason, enzymatic solutions are ideal for endoscopic equipment. Depending on the solution, these enzymes can be combined with other chemical agents for instruments to soak. The enzymes used in these cleaners break down proteins on any surface it comes in contact with; therefore, care must be taken while using these cleaners to avoid skin contact, accidental ingestion, contact with mucous membranes, or inhalation if aerosols are used.



Enzymatic cleaner, a mixture of protease, amylase, lipase, carbohydrase, and "proprietary enzymes." This is mixed with (non-sterile) water according to the manufacturer's instructions- the mixture is changed daily.

Glutaraldehyde: This solution, also known as "Cidex" is a chemical solution that can be used for cold disinfection. It requires a pH >7, with greatest efficacy at pH 9-10. Items are submerged in a ≥2% solution for 20-90 minutes at 20 ºC to achieve high-level disinfection or 10 hours to achieve sterility. This solution can be reused for 14-30 days. Note that this solution can be quite toxic, therefore proper PPE and procedural care must be taken to avoid inhalation or skin contact. Although it is widely used in the healthcare setting, especially for disinfection of endoscopic equipment, this solution may not be legal in all countries.

2% Glutaraldehyde solution: this is not to be diluted. .

Hydrogen peroxide can be used to achieve high-level disinfection via a 7.5% solution for 30 minutes at 20 ºC. Sterilization can be obtained by increasing contact time to 6 hours. This solution can be reused for 21 days.

Peracetic acid at a concentration of 0.2% at 50-56 ºC can be used to achieve sterility when items are submerged for 12 minutes. A solution of 7.35% hydrogen peroxide with 0.23% peracetic acid can be used to achieve high-level disinfection at 20 ºC for 15 minutes. Increasing exposure time to 3 hours is effective for sterilization. In addition, this solution can be reused for 14 days.

Ethylene oxide: This is a poison gas that very effectively sterilizes laparoscopic equipment as well as plastic materials since it does not use heat or moisture. A concentration of 700 mg/L can sterilize at 38 ºC (100.4 ºF) in eight hours and at 54 ºC (129 ºF) in four hours. However, this method is not readily available, as it requires a special ethylene oxide chamber, and the used gas must be destroyed either via a sulfuric acid scrubbing mechanism or catalytic oxidation. In addition, this gas is explosive. Therefore, in resource-limited settings other methods should be used for disinfecting/sterilizing certain equipment such as rubber, fragile plastic or laparoscopic cameras.

PRACTICE

Given that this topic is vast and sprawling, focus will be placed on a few topics related to common practices: general operating room layout for optimal sterilization, a case-based walk through of general steps to be taken after an operation, and finally a few tips for operating common sterilization tools. Remember, the steps to achieve sterilization include cleaning, decontamination / cleaning, disinfection, and sterilization.

Operating room and sterilization area design.

The operating room has a network of support areas/rooms that allow it to function: decontamination area, packing area, sterilization area, and sterile supply room. Each of these distinct zones are necessary within your operating facility to keep operations going.

Decontamination area: This area is the first stop after an operation is completed. It has a sink used for mechanical removal of any bioburden, via high pressure water, air, or manual scrubbing. It also has an area for submersion disinfection (i.e enzymatic cleaner or glutaraldehyde.) It is physically separated from the other areas to reduce risk of cross-contamination.

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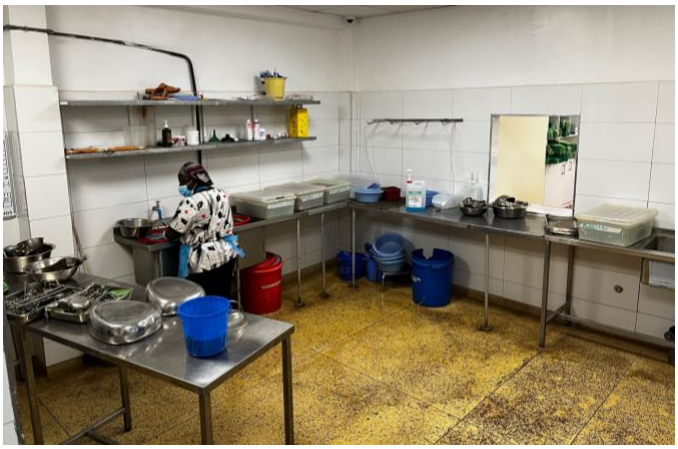

The decontamination area is well ventilated, well drained, with areas for disposing of contaminated waste and washing soiled instruments.

Packing area: This area, which is separate from the decontamination area, has large surfaces such as tables where disinfected instruments can be sorted, packed and wrapped. This packing area also houses any disposable items, such as paper and gloves, as well as linens.

In the packing area, clean and dry instruments are wrapped for sterilization. In this instance, the table behind the technician contains instruments that are air-drying (Red arrow.) Once they are dry they are transferred to this area for wrapping.

Sterilization area: The sterilization area is where the autoclaves are located. Ideally, multiple autoclaves would be operating to allow for a more efficient sterilization process, as autoclave cycles are time-consuming and require an adequate drying time before sterile packs can be handled and transported.

Wall-mounted autoclaves in the sterilization area, with a trolley to support the rack as it is being unloaded.

Sterile supply room: After sterilization has been achieved, the items must be properly stored. However, it is important that the sterile packs are completely dry before moving them to the sterile supply room. Moisture encourages microbial growth, and microbes can even travel to the inside of the sterile packs causing contamination.

Instruments are stored in a cool, dry area with labeled shelves for easy retrieval.

Case-based example: Decontamination to Sterilization to Storage

1. **Initial handling, cleaning of contaminated items, and movement to decontamination area**

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At the conclusion of an operation, all instruments (including unused instruments) must be handled as if they are contaminated and moved to the decontamination area. Any tubing, suction containers, and/or fluid-filled basins must also be placed on a cart, covered with a sheet, and then moved to the decontamination area. Any fluids from this cart can be offloaded into a fluid hopper once in the decontamination area.

Once in the decontamination area, proper personal protective equipment (PPE) should be donned; this includes face and eye protection, a thick apron, thick gloves, as well as a long-handled brush. If possible, forceps should be used to empty the instruments from the cart or, more simply, instruments can be dumped out onto a towel. Care should be taken to never reach into any container or tray without looking first; it should always be assumed that each tray or container has sharp items capable of breaking skin and causing infection. Any biohazard or soiled linens should be placed in the appropriate receptacle.

In this instance, the scrub technician has separated the instruments that were not used during the surgery. They are placed in an enzymatic solution to soak in case any unknown contamination occurred during the surgery.

Soiled linens are soaked in this decontamination solution before being taken to the laundry for washing.

A note about instruments: Stainless steel is not actually stainless and can experience corrosion from biological and chemical liquids. As a rule of thumb, any soiled instruments should be cleaned within twenty minutes of contamination. If immediate cleaning is not possible, organic matter such as blood or tissue can be prevented from drying on the surface of the instrument by submerging dirty instruments in water containing enzymatic detergent. During a surgery, instruments can be submerged in sterile, distilled water to clean and remove blood or other visible debris while not in use.

The leading cause of pitting/stained surgical equipment is moisture (pus, blood, cleaning solutions). Use of housekeeping cleaning solutions, laundry or dish detergent, and iodine based solutions can also lead to staining and pitting of surgical equipment. Make note of any instrument in disrepair and set it to the side.

2. Cleaning while in decontamination area

All reusable instruments, tubes, suction devices, and packing trays used during an operation must be cleaned thoroughly prior to disinfection or sterilization. The presence of biomaterial on the surface of equipment hinders the sterilizing capability of autoclaves and can inactivate chemical sterilants and disinfectants. The general workflow is to disassemble and sort, spray/soak, scrub, rinse, dry, lubricate, and then disinfect or sterilize.

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Disassembly: All equipment or devices with removable parts should be disassembled according to the manufacturer's guidelines to facilitate removal of all organic debris and allow better access to all parts of the instrument by the disinfectant or sterilant. Disassembled parts should be kept together for easy reassembly later on. Sorting equipment into groups that will be processed in the same way helps to streamline the overall process.

Spray/Soak: After disassembly and sorting, items are placed in the sink and sprayed with water (preferably high pressure) and/or compressed air to remove large chunks of debris. Items can then be soaked in an enzymatic cleaning solution with a neutral pH for 10-20 minutes to help remove debris from hard-to-reach places and make the cleaning process easier and more effective. Extensive soaking, such as overnight soaks, can damage equipment and should be avoided.

Near the washing area, contaminated instruments are placed in the enzymatic solution before being scrubbed.

Scrub: If available, an ultrasonic cleaner should be used to mechanically scrub items after spraying down and soaking them. Manual scrubbing may be used if this is not an option. It is important to note that low-mineral water (distilled or reverse osmosis water) is essential for cleaning instruments because damage can be caused by high mineral content water. Saline should also never be used in the cleaning process. A nylon brush can be used to manually scrub organic debris from instruments. If debris is still present, a stainless steel brush can be gently used, with care being taken to prevent scoring or scratching of metal (which creates crevices for organisms to hide, grow, and form biofilms).

As seen here, the technician has donned an impermeable gown and thick gloves (as well as a mask and eye protection.) The needle holder in her left hand has been opened and she is scrubbing the rough surface inside its jaws with a heavy brush.

Even if all removable sharps (scalpel blades, needles) have been removed, the technician must take special care because some instruments can still cause injury. Examples include penetrating towel clips (shown here) osteotomes, and other sharp instruments.

Rinse: All equipment/devices should be thoroughly rinsed after scrubbing to remove any residual detergent. Residual detergent can react with sterilizing solutions and disinfectants and hinder the disinfectant or sterilization process.

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Dry: After thoroughly rinsing, equipment must then be allowed to completely dry, either by hand or air-dried, for maximal efficacy of chemical disinfectants.

Here, cleaned but still wet instruments are passed through a window from the decontamination area to the sterilization area to dry before being wrapped for sterilization.

Lubricate: After the instrument has been cleaned of visible debris, a process called gross decontamination, surgical instrument lubricant should be applied to any mobile joints or hinges before sterilization.

Do not use industrial lubricants like WD40 or any oil-based lubricants. Instead, water soluble lubricants that are steam-permeable should be used.

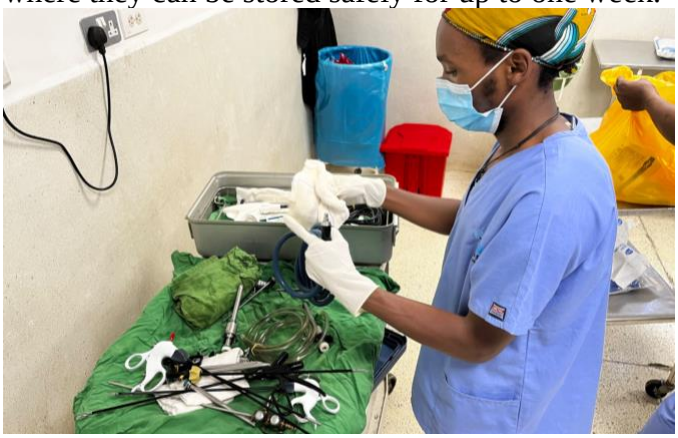
At this point, semi-critical patient care items, such as endoscopes, should undergo high-level disinfection. Critical medical and surgical items should be packaged for sterilization.

3a. High-level disinfection.

Semi-critical patient care items that have been properly cleaned, rinsed, and dried should be soaked in a high-level disinfectant for the minimum effective time and concentration that has been determined for that particular chemical disinfectant. Lengthy submersion may cause damage, especially to finer instruments.

Laparoscopic instruments, after being scrubbed, rinsed and dried, are soaked in glutaraldehyde solution for the time prescribed by the manufacturer.

It is important to note that *unwrapped* instruments must be used either immediately after sterilization, or placed in a dry, covered sterile tray, where they can be stored safely for up to one week.



After soaking in glutaraldehyde, laparoscopic instruments are rinsed in sterile saline and allowed to dry using strict sterile technique. A technician then loads them into a sterile container.

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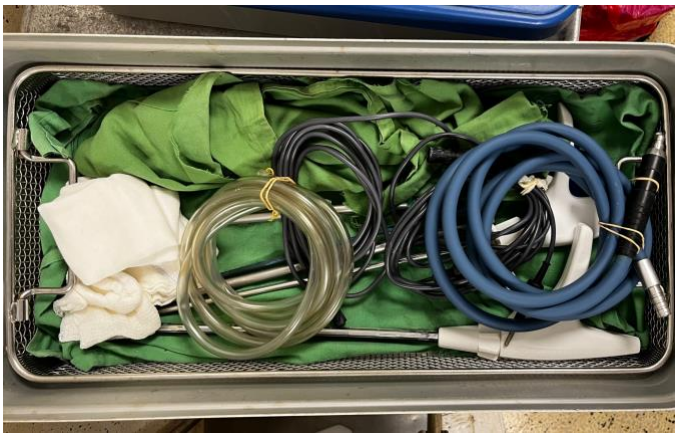

Laparoscopic instruments that have been treated as above and placed in a sterile container. When needed, they are retrieved using sterile technique and placed on the surgical table.

High-Level Disinfectant or Sterilant	Concentration	Parameters for high-level disinfection	Parameters for sterilization
Hydrogen peroxide	7.5%	30 minutes at 20 °C	6 hours at 20 °C
Peracetic acid	0.2%	n/a	12 minutes at 50-56 °C
Glutaral-dehyde	≥2.0%	20-90 minutes at 20-25 °C	10 hours at 20-25 °C
Ortho-phthalaldehyde	0.55%	12 minutes at 20 °C	none
Hydrogen peroxide/ peracetic acid	7.35%/ 0.23%	15 minutes at 20 °C	3 hours at 20 °C

Common disinfectants and sterilants and their concentrations and exposure times.

Avoid using any benzyl ammonium chloride solutions with instruments that have tungsten-carbide inserts.

If your surgical theater is set up with a dedicated decontamination and clean area, ensure that soiled items are loaded from the decontamination side and then (after washing) clean instruments are removed from the clean side.

3b. Packing and sterilization

After decontamination and disinfection, the items can now be sterilized by equipment such as an autoclave. First, a pack must be created.

A thoughtful strategy when making packs can help reduce the "wear and tear" on instruments. By creating smaller packs that can be added together to make a larger unit, unnecessary future processing can be avoided, which in turn minimizes repairs.

When packing surgical instruments into sterilization pouches, ensure that the instruments are open and in their UNLOCKED position, which allows steam to reach all active surfaces, and prevents cracks from heat expansion. Locking jaws/blades will prevent proper sterilization and may damage the instrument's box joints during the heating sterilization process. Ensure that any sharp tips are covered, yet are covered in a way that still allows steam to penetrate the covering.

Use disposable paper: Packs can be created out of individual instruments or entire sets of instruments, which will then be placed in the autoclave to achieve sterilization. Pouches should not be overpacked with instruments, and there should be adequate room in the pouch for steam to reach the surfaces of the instruments.

The technician here is using a combination of paper and cloth. He folds the instrument tray on all four sides, covering it completely.

Here, he has secured the wrapping with both tape and string. The instrument set is labeled as below.

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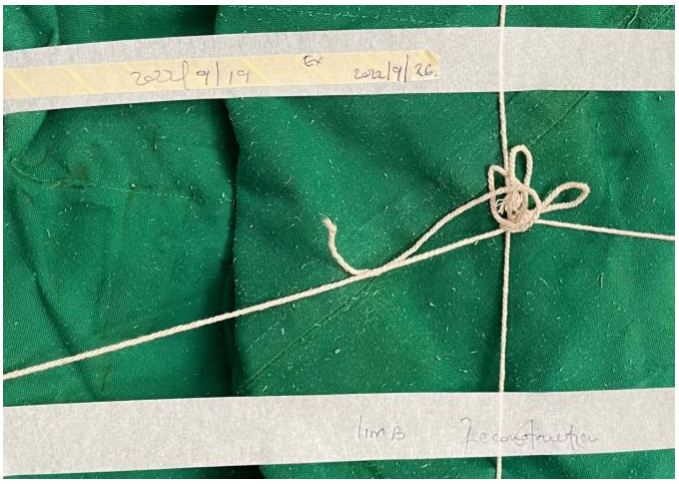

The smaller strip of tape with the date on it is autoclave tape: the fine white stripes on it will turn black when exposed to sufficient temperature and pressure to sterilize the instruments. The date of sterilization and expiry are noted in the upper part of the photo. The name of the instrument tray is noted on the lower part.

Using the autoclave: After the cleaned and decontaminated, but non-sterilized packs have been created, the pouches may be placed into the autoclave to be sterilized. These packs, however, should not be *stacked* because it will block steam from circulating throughout the chamber. Once properly packed, the autoclave may be started. Depending on the model of the autoclave, once the autoclave has cycled, the door may be opened *slightly* (~ 1cm) to allow any steam to escape. The door should not be opened fully as condensation can form on the instruments and pouches as cold air rapidly enters the autoclave. After running the dry cycle, sterile tongs should be used to remove the dry and sterile items.

Storage after sterilization: The sterilized packs should be completely dry on the wire racks before moving to sterile storage. If instruments are wrapped, they can be stored indefinitely in a warm, dry and closed space such as a cabinet (provided the pack remains intact and dry).

Sterilization Tips and Procedures for Various Appliances

1. Commercial or Domestic Pressure Cookers

A simple electric pressure cooker autoclave. Source: Viv Rolfe, CC BY-SA 4.0 https://creativecommons.org/licenses/by-sa/4.0, via Wikimedia Commons

As discussed earlier, steam sterilization is more effective than dry heat, and use of steam under high pressures is effective at killing spores, provided the appropriate parameters of temperature, pressure, and time are used. Most commercial pressure cookers can sterilize effectively since they can achieve the pressure, temperature, and time parameters of 15 psi, 121 ºC, and 30 minutes that are needed for sterilization. Store-bought, or home pressure cookers are relatively low-cost; however, most are unable to reach the temperature and pressure requirements needed to kill spores. One study demonstrated sterilization using an "Instant Pot," home pressure cooker, but it required a duration of 150 minutes to kill the spores in the test sample. The extended time requirement has to be taken into account when operating in low-resource settings where electricity may not be reliable. One company has created a pressure cooker, the EcoClave, that can sterilize instruments in 30 minutes using burning wood as the fuel source, making it a potentially ideal option for sterilization in very low resource settings (source.)

When operating any pressure cooker, all manufacturing instructions should be followed closely for proper safety. First, all instruments must be cleaned and decontaminated as discussed previously. A barrier, such as a trivet or bowl, should be placed between the inner surface of the pressure cooker and the items being processed. Items to be sterilized can also be placed into sterilization packs

or bags, just like when using an autoclave. Autoclave tape can also be used over the packs to ensure that the proper temperature for sterilization has been achieved. When placing items inside the cooker, adequate spacing should be maintained to allow proper circulation (just like an autoclave). Enough distilled water should be added to reach a height of 2.5 cm from the bottom of the pot for steam production. The cover should then be placed and properly sealed. At this point, the external heat source should be applied to the pressure cooker, either wood fire, gas stove, or electric burner. (For the Instant Pot, the device must be plugged into an electric outlet and operating instructions followed for a total cook time of 150 minutes). After heating has started, steam should be allowed to exhaust for about four minutes before closing the outlet.

The pressure gauge should be watched carefully. When the pressure has reached the green area, or 15 psi, sterilization has begun. The instruments should be allowed to process for as long as 35 minutes. After sufficient processing, the pressure cooker should be removed from its heating source and depressurized by opening the steam outlet. No skin should be in contact with the hot steam that escapes through the valve or serious burns can occur. Once the gauge has reduced to zero, the pressure cooker can be opened by lifting the lid in a direction that is away from any person's face or body.

Never open a pressure cooker under pressure.

Once items are removed, they must be dried properly before storing. Items can be placed either on a wire rack (covered with a fly net) or in an oven to dry (~200 degrees for 6 hours). Once dry, these items can be placed in a dated and labeled ziplock bag.

Some *home* pressure cooker units cannot get hot enough or attain adequate pressures for sterilization. In fact, they may fail and rupture. However, the Instant Pot brand was shown to effectively achieve sterilization after 150 minutes of cook time.

2. Large Autoclaves

A large electronically controlled autoclave in a hospital in a resource-rich country.

When using autoclaves, one of the most important components of maintenance is regular use and testing. When preparing to use an autoclave, appropriate PPE should be used, and overcrowding of the packs should be avoided. Autoclave pouches that can be penetrated by steam should be used, and the packs should not be stacked on top of one another. If glass is being placed in the autoclave, it should be inspected for cracks to avoid shattering. If liquids are to be sterilized, a secondary container should be used to house the primary container to catch any spills. Autoclave tape is often used as a visual marker to ensure that adequate temperature for sterilization has been achieved during the autoclave cycle.

<u>Considerations for special equipment</u>

This chapter has focused on general instructions for routine sterilization of common surgical instruments. However, there are special considerations for other tools such as endoscopic equipment.

Endoscope sterilization: Endoscope sterilization is a unique process, requiring different steps than a metal instrument like a clamp. These

instruments also generally have a much higher bioburden and microorganism load than other items due to the nature of their use (i.e colonoscopy). Therefore extra-care must be taken to properly/maximally disinfect/sterilize the equipment while also maintaining its function. An additional chapter will be dedicated to processing of special equipment.

Further Reading:

United States Centers for Disease Control (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).
https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

The Eco-Clave wood burning autoclave by MedAid International:
https://medaid.co.uk/wp-content/uploads/2021/11/EcoClave-Booklet-2021.pdf

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