

Slide 1	Welcome to Cleaning, Disinfection & Sterilization, Part 2 of 2.
Slide 2	One way to achieve sterilization is with steam. Steam sterilization uses 4 parameters to achieve sterilization. These include the amount of steam, the time that it has contact with the object(s), the temperature it reaches, and pressure. In terms of processes, steam sterilization is the oldest, safest, cheapest, and the best understood. The advantages are, for example, similar to pasteurization, you are only using water, which is nontoxic; it is readily available; it is easy to perform steam sterilization; it is fairly easy to control; and it is known to be consistent and reliable. While steam sterilization is the preferred method of sterilization, it can not be used on instruments that can be damaged by heat, steam, pressure or moisture.
Slide 3	If you are going to claim that something is sterilized, you have to be able to confirm it; therefore a biological monitor has to be used with steam sterilization. The biological monitor is <i>Geobacillus stearothermophilus</i> (formerly known as <i>Bacillus stearothermophilus</i> ) and it must be put into the sterilizer weekly and with every implantable device that is sterilized. In addition to using the biological monitor, chemical indicators must be used with each item sterilized. A chemical indicator will also tell you whether the steam was at the correct level, the required temperature was reached, the time was adequate, and the pressure was adequate. In addition, the temperature must be monitored with each load, either with a log book or through the use of computer systems that check each parameter to ensure the quality of each load. This information, particularly the biological indicator required, is almost always on the CIC exam in one form or another.
Slide 4	There are two basic types of steam sterilizers. One type is called the gravity displacement and the other is called a high speed pre-vacuum sterilizer.
Slide 5	This slide shows the required sterilization cycles for two types of steam sterilizers. There is no way around these numbers except to memorize them and they are often asked on the CIC exam. For the gravity displacement sterilizer, items must be run at 121° C or 250° F for 30 minutes. If it is a pre-vacuum sterilizer, then items must be run at 132° C or 270° F for 4 minutes.
Slide 6	A second type of sterilizer is the dry heat sterilizer, which oxidizes the cell parts, thus killing the organism. The advantages are that the heat penetrates the cell very well and it doesn't corrode metal equipment or sharp objects. Dry heat sterilization is also non-toxic and has a relatively low operating cost. The disadvantages are that the process is slow and therefore takes a lot of time as well as energy to accomplish. It should only be used on equipment or materials that might be damaged by steam or are impenetrable by steam. Examples of materials or objects amenable to dry heat sterilization are powders, petroleum products, or sharp instruments.
Slide 7	Here again is another set of temperatures which may or may not be on the CIC exam. For the dry heat sterilizer, the biological indicator used is the spore of the <i>Bacillus atrophaeus</i> (formerly <i>Bacillus subtilis</i> ), which is similar to anthrax but is not pathogenic. It is the required biological monitor to use for dry heat sterilizers.
Slide 8	The third kind of sterilizer is the ethylene oxide or (ETO) sterilizer. Ethylene oxide is a colorless, odorless, flammable, and explosive gas. It is commonly used to sterilize objects that can't be steam sterilized. ETO has 4 parameters, as with the other sterilizers, and includes concentration of gas, temperature, humidity, and exposure time. What is good about ETO is that it can inactivate all microorganisms.

Slide 9	ETO's primary advantage is that it can sterilize heat or moisture sensitive medical equipment without destroying it. Some devices are very expensive and are unable to be sterilized with steam or with dry heat. Therefore they must be sterilized with ethylene oxide (ETO). However there are many disadvantages to this process, because it is explosive, flammable, and results in contact exposure issues for healthcare personnel. Thus, it requires an aeration time of 8-12 hours after each load. The process is very expensive and requires monitoring patients and staff so that they don't become exposed to ETO. The process must be performed where there is an area with low patient or staff traffic.
Slide 10	So far we have discussed the physical processes of sterilization and included steam, dry heat, and ethylene oxide sterilizers. Next we move onto the chemical processes to achieve sterilization or disinfection with disinfectants or sterilants. Two popular brands of chemical sterilants are Cidex and Cavicide, with the active agent, glutaraldehyde. There are several sizes of systems using glutaraldehyde that are capable of using chemicals to sterilize/disinfect instruments including endoscopes. Glutaraldehyde can destroy spores but it depends on the contact or exposure time whether sterilization or disinfection is achieved. This is a very important point.
Slide 11	Just as the effectiveness of physical processes and chemical processes require monitoring, the same is true for chemical sterilants. For example, outbreaks of <i>Pseudomonas</i> with improperly cleaned laparoscopes or an outbreak of <i>Serratia</i> due to an improperly cleaned endoscope have been reported in the literature. The scope needs to be placed in an active solution of glutaraldehyde that has not been diluted, it needs to be rinsed with sterile water and dried thoroughly. If any of these steps are not completed, then the scope may be inadequately disinfected. Therefore, it is important to think about all the steps in this process to achieve sterilization. Sterilization procedures should be assessed using a combination of mechanical, biological and chemical indicators. Newer models of Automated Endoscope Reprocessors or AERs as they are called, may offer benefits over the older models in relation to these problematic issues. Disinfection and sterilization of endoscopes is an important issue. For this reason, I have included Supplemental Reading #2, the set of guidelines regarding reprocessing of flexible gastrointestinal scopes, from 2011.
Slide 12	The mechanical indicators for steam sterilization include the daily assessment of cycle time, temperature and pressure. Mechanical indicators for ETO sterilization include daily monitoring of time, temperature and pressure. Two essential elements of ETO sterilization can not be routinely monitored in the health care sterilizers: gas concentration and humidity.
Slide 13	Let's sum up the biological indicator requirements. You need one for ethylene oxide, dry heat, and steam. The biological indicator is made with a spore. For steam, the indicator is the <i>Geobacillus stearothermophilus</i> , for ETO and dry heat it is <i>B. atrophaeus</i> . It is important to commit these indicators to memory.
Slide 14	Chemical indicators have the advantage of providing an immediate indication of whether any of the parameters were met. But because they are chemical indicators, they have a tendency to produce false positives and false negatives. This is not true for biological indicators (BI). In the U.S., Class 6 chemical indicators were introduced after the CDC guidelines were issued. Class 6 emulating indicators (also known as cycle specific indicator strips) are not a substitute for a biological indicator. No professional organization has recommended the use of Class 6 emulating indicators as a substitute for biological indicators, and there are no data that demonstrate that a Class 6 indicator mimics a biological indicator at suboptimal sterilization times and/or temperatures.

Slide 15	Let's review the levels of decontamination. Cleaning is the lowest level, sterilization is the highest level and is an absolute term. In the middle we have sanitizing, low, intermediate, then high-level disinfection.
Slide 16	There are several factors that effect cleaning and sterilization. One such factor is the complexity of the device, (e.g., is it hinged, does it have a lumen or inner chamber, does it have many surfaces?) How many and what type(s) of organisms are present? The types of organisms on the item are important, for example, whether it is TB or Staph, as they require certain disinfectants to be eliminated. The innate resistance to the sterilization process and disinfectants differs depending on the organism. Another factor is whether there is organic material left on the object. The type of decontamination method used is also an effecting factor. The concentration of the disinfectant used is also an important factor. With the exception of iodophors, the more concentrated the disinfectant, the more effective it is. Finally, the presence of biofilms can negatively affect the effectiveness of a disinfectant.
Slide 17	Let's start with a very simple device. This is a bed pan and you can see that it has pretty smooth surfaces, no hinges, and not many places where organisms can hide. It can therefore be effectively cleaned, fairly easily.
Slide 18	Then there are more complicated instruments, such as surgical tools, which have more surfaces, more moving parts, and many have hinges. Therefore it is harder to remove organic material from these devices.
Slide 19	An even more complicated device is something like a scope, because there is an inner lumen or cavity, there are complicated parts, it has a camera, and a soft rubber tube that is inserted into the patient. There are many places and steps where contamination can occur when you are cleaning these scopes, as we discussed several slides ago.
Slide 20	"Bioburden" is defined as the number and types of viable (or living) organisms which contaminate an article or object. When they are measured, they are expressed as a total count of either bacteria or fungus per single colony-forming unit per single article.
Slide 21	The definition of a "biofilm" is an accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed. Biofilm accumulation results in microbial communities that can nor be easily removed from objects. Biofilms reduce the efficacy of sterilization by impairing exposure of the sterilant to the microbial cell.
Slide 22	How do we know what needs to be sterilized or what can be low, intermediate, or high level disinfected? One way is to use the Spaulding system, which is a classification scheme based on the assumption of the risk involved with devices used on a patient. The risk of infection determines how rigorous you will be when cleaning a device. Let's discuss the system and it will perhaps facilitate your understanding of these concepts.
Slide 23	The Spaulding scheme has 3 categories: critical, semi-critical, and non-critical. A critical item is one that enters sterile tissues or the vascular system (e.g., intravenous catheter or dialysis catheter). Obviously if an object is inserted into sterile tissue, such as a vein, or artery, it must be sterile. Semi-critical refers to objects that contact mucous membranes or non-intact skin and must be high-level disinfected. Non-critical objects are those which contact intact skin, but not mucous membranes, and must receive low-level disinfection. We will go into each of these in more detail. Please note, when you are going through these 3 levels, that contact times are different for

	chemical sterilants, depending upon whether sterilization, high-level or low-level disinfection is desired. This is a very important point.
Slide 24	Critical items require sterilization and this can be achieved by three methods: 1) steam 2) ETO or low temperature sterilization and 3) (although rarely) with chemical sterilants (e.g., greater than 2.4% glutaraldehyde, 7.5% stabilized hydrogen peroxide, and 0.2% peracetic acid.) Examples of critical items include surgical instruments, implants, needles, cardiac catheters and urinary catheters.
Slide 25	This slide shows examples of critical items that have to be sterilized.
Slide 26	Semi-critical items are those that come into contact with either mucous membranes or non intact skin. These items must receive at least high-level disinfection with either: 1) wet pasteurization or 2) chemical disinfection (e.g., glutaraldehyde, hydrogen peroxide, Ortho-phthaldehyde, and peracetic acid with hydrogen peroxide). Steam sterilization is preferred method of between-patient processing of heat-stable medical instruments. Examples of semi-critical items are endoscopes, bronchoscopes, respiratory therapy equipment and anesthesia equipment. These items should be free of all micro-organisms; however, small numbers of bacterial spores are permissible. Ideally, laparoscopes and arthroscopes entering sterile tissue should be sterilized between patients, but in the U.S., these items frequently undergo only high-level disinfection.
Slide 27	Examples of semi-critical items are as follows: on the left is a scope, the middle shows respiratory therapy equipment and on the right is a laryngoscope (a piece of anesthesia equipment) with several different-sized blades.
Slide 28	Additional recommendations for semi-critical items addresses the need for a surveillance system to identify potential outbreaks and the steps to take. For example, if a cluster of endoscopy-related infections occurs, then you need to investigate how the pathogen is being spread and what the reservoirs are. This ongoing surveillance may assist in finding problems with sterilization or disinfection procedures.
Slide 29	Non-critical items are those that come into contact with intact skin but not mucous membranes. Non-critical items require use of low-level disinfectants. There are several choices: ethyl or isopropyl alcohol; sodium hypochlorite at a concentration of 100 parts per million; or phenolic, iodophor or quaternary ammonium germicidal solutions. Examples of items that may receive low-level disinfection are bedpans, blood pressure cuffs, crutches, bedrails, linens, and bedside tables.
Slide 30	On this slide we have a picture of an environmental services cart containing disinfectants, a stripped bed ready to be cleaned, a bedpan, blood pressure cuff and a stethoscope.
Slide 31	This slide contains many different examples of disinfectants. Practicing infection preventionists need to be familiar with these agents, what they can be used for, advantages, and disadvantages. I encourage those of you who wish to sit for the CIC exam or who are new infection preventionists, to read more about each of these agents.
Slide 32	It's important to note the differences between sterilization and disinfection. Often, the term "sterilization" is mistakenly used to refer to a process which is actually disinfection. Sterilization destroys or eliminates all forms of microbial life, including spores whereas disinfection is not sporicidal. The problematic item requiring a specific sterilization process, is the prion (Creutzfeldt-Jakob Disease).
Slide 33	There are issues that need to be considered when determining which disinfectants are used in healthcare facilities, including known biohazards, appropriate patient populations, and their inactivation in the presence of organic materials. One example is that phenolic agents are not

	recommended for use in nurseries, to clean bassinets, as their use has been linked to a condition called hyperbilirubinemia, in infants. Each disinfectant has a specified surface contact time on the label, sometimes as long as 10 minutes.
Slide 34	There is a Category IA Recommendation from the 2008 Guideline regarding processing of patient care equipment. Use of standard sterilization & disinfection procedures for patient-care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood or other body fluids from persons infected with pathogens in any of the categories listed on this slide, except for prions.
Slide 35	This figure shows the order of resistance of microorganisms to disinfection & sterilization and the level of disinfection or sterilization. As you can see, prions are the most resistant to these efforts. (Source: "CDC Guidelines for Disinfection & Sterilization in Healthcare Facilities, 2008", page 108).
Slide 36	Prions are transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including Creutzfeldt-Jakob disease (CJD) in humans, bovine spongiform encephalopathy (BSE aka "Mad cow disease") in cattle, and other neurodegenerative diseases in sheep and goats. Prions are unlike any other infectious pathogens because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prions are extremely resistant to inactivation by sterilization processes and disinfecting agents. This tissue slide shows sponge-like lesions in the brain tissue of a classic CJD patient. This lesion is typical of many prion diseases.
Slide 37	The high resistance of prions to standard sterilization methods warrants special procedures in the reprocessing of surgical instruments. Special prion reprocessing is necessary when reprocessing critical or semicritical medical devices that have had contact with high-risk tissues from high-risk patients. After the device has been cleaned, it should be sterilized by either autoclaving (i.e., steam sterilization) or using a combination of sodium hydroxide and autoclaving, using one of the four options below: <ul style="list-style-type: none"> <li>• Option 1 - autoclave at 134°C for 18 minutes in a prevacuum sterilizer</li> <li>• Option 2 - autoclave at 132°C for 1 hour in a gravity displacement sterilizer</li> <li>• Option 3 - immerse in 1N NaOH (1N NaOH is a solution of 40 g NaOH in 1 liter of water) for 1 hour; remove and rinse in water, then transfer to an open pan and autoclave (121°C gravity displacement or 134°C porous or prevacuum sterilizer) for 1 hour</li> <li>• Option 4 - immerse instruments in 1N NaOH for 1 hour and heat in a gravity displacement sterilizer at 121°C for 30 minutes; clean; and subject to routine sterilization. These source of this information is Chapter 21 of the APIC Text "Cleaning, Disinfection &amp; Sterilization", pages 13-16.</li> </ul>
Slide 38	There is also a set of guidelines from the W.H.O. regarding this issue, in the section entitled "Annex III Decontamination methods for Transmissible Spongiform Encephalopathies". In the introduction to this section, the authors state, The following recommendations are based on the best available evidence at this time and are listed in order of more to less severe treatments. These recommendations may require revision if new data become available." It is important to note that these guidelines were published in 2003 based on a working group's work in 1999. The link to these guidelines is on this slide.
Slide 39	With advances in technology, newer agents and methods have been introduced into this area. The first is ortho-phthaldehyde, a chemical sterilant comparable to glutaraldehyde, but requiring a shorter contact time. The next is surfacine, a persistent antimicrobial agent that can be used on animate or inanimate objects. Surfacine uses silver iodide and is resistant to forming biofilm. A sterilization process using ozone was approved by the FDA in 2003. The main advantage of this process is that it relies on oxygen, water, and electricity. There are no toxic byproducts and the operating temperatures are lower at 30-35 degrees Celsius (C). Endoclens is a liquid chemical sterilization system for cleaning scopes, using a combination of formic acid and hydrogen peroxide. It can process 2 scopes at one time. Only instruments that can be immersed in fluid can be processed this way. There is an Attest rapid readout monitor for ethylene oxide-processed items,

	<p>ready in 4-hours compared to other biological indicators' length of 48 hours. This prevents the recall of sterilized items that did not achieve sterilization. Finally, the plasma sterilizer uses hydrogen peroxide and has a reduced cycle time, without leaving a toxic residue. A selected number of newer technologies has been presented, and as you can see, each has advantages and disadvantages to comparable methods or systems.</p>
Slide 40	<p>One additional recent technology is the use of Hydrogen Peroxide Vapor or HPV for both room decontamination and for low temperature sterilization.</p> <p>Advantages of HPV include:</p> <ul style="list-style-type: none"> <li>•Surfaces and equipment decontaminated</li> <li>•Decrease incidence of disease (<i>C. difficile</i>)</li> <li>•Residue free and does not give rise to health and safety concerns (aeration units convert HPV into oxygen and water)</li> <li>•Uniform distribution via an automated dispersal system</li> <li>•Useful for disinfecting complex equipment and furniture</li> <li>•Efficacious (reliable biocidal activity) against wide range of pathogens</li> </ul> <p>Disadvantages of HPV include:</p> <ul style="list-style-type: none"> <li>•Only done at terminal disinfection (not daily cleaning)</li> <li>•Rapid recontamination of the environment</li> <li>•All patients must be removed from the area</li> <li>•Decontamination takes approx 3–5 hours (bed turnover time-72 minutes)</li> <li>•HVAC disabled to prevent unwanted dilution of HPV during the exposure; room sealed with tape</li> <li>•Contribution of the environment to disease transmission ~5%</li> </ul> <p>Please see Required Reading #2, pages 21-22 for a full list of advantages and disadvantages.</p> <p>On this slide are pictures several different HPV systems.</p>
Slide 41	<p>Up until this point, we have discussed cleaning, sterilization and disinfection in relation to inanimate objects. An antiseptic is defined as a chemical germicide that prevents or arrests the growth or action of microorganisms on living tissue, either by inhibiting their activity or destroying them. Antiseptics should not be used on inanimate objects. Antiseptics are regulated by the Food and Drug Administration and are registered as drugs. Hand hygiene agents, surgical scrubs, and agents used to clean the skin before surgery are all examples of antiseptics. You will be learning more about antiseptics in the lectures on Hand Hygiene.</p>
Slide 42	<p>This week we have covered numerous principles and a great deal of information regarding cleaning, disinfection, and sterilization. Before you leave this week's materials, make sure that you have read the Required Readings. Remember that there is a quiz due by Sunday at 9 PM, worth 5% of your course grade. That quiz is designed to reinforce the concepts from both sets of lecture materials and the Required Readings.</p> <p>This concludes "Cleaning, Sterilization &amp; Disinfection, Part II lecture.</p>