### ELEVEN

### STERILIZATION<sup>1</sup>

KEY CONCEPTS you will learn in this chapter include:

- What the common methods of sterilization are
- What the advantages and disadvantages of these methods are
- How to store sterilized items
- What the advantages and disadvantages of other methods of sterilization are

### BACKGROUND

# Sterilization destroys all microorganisms, including bacterial endospores.

Sterilization should be used for instruments, surgical gloves and other items that come in direct contact with the blood stream or normally sterile tissues (Spaulding 1939). It can be achieved by high-pressure steam (autoclave), dry heat (oven), chemical sterilants (glutaraldehydes or formaldehyde solutions) or physical agents (radiation). Because sterilization is a process, not a single event, all components must be carried out correctly for sterilization to occur.

### Effectiveness

Note: Although rinsing an item with alcohol and then igniting it with a match (flaming) sometimes is suggested as a method of sterilization, it is not effective!

- steam sterilization, high pressure. The effectiveness of any method of sterilization is also dependent upon four other factors:
  - 1. **The type of microorganism present.** Some microorganisms are very difficult to kill. Others die easily.

To be effective, sterilization requires time, contact, temperature and, with

- 2. **The number of microorganisms present.** It is much easier to kill one organism than many.
- 3. The amount and type of organic material that protects the microorganisms. Blood or tissue remaining on poorly cleaned instruments acts as a shield to microorganisms during the sterilization process.
- 4. The number of cracks and crevices on an instrument that might harbor microorganisms. Microorganisms collect in, and are protected by, scratches, cracks and crevices such as the serrated jaws of tissue forceps.

Finally, without thorough cleaning, which removes any organic matter remaining on the instruments that could protect microorganisms during the

<sup>&</sup>lt;sup>1</sup> Adapted from: Tietjen, Cronin and McIntosh 1992.

sterilization process, sterilization cannot be assured, even with longer sterilization times.

### METHODS OF HEAT STERILIZATION

#### Remember: When

instruments and equipment are sterilized by highpressure steam (autoclaving), it is essential that steam reach all surfaces. For example, steam sterilizing closed containers will sterilize only the outside of the containers!

Note: High-speed (flash) prevacuum sterilizers are operated at higher temperatures (134°C/275°F). Sterilizing time for unwrapped instruments by this method is shorter, only taking 4 minutes. Flash sterilization is usually used for individual items. High-pressure, saturated steam using an autoclave, or dry heat using an oven, are the most common and readily available methods used for sterilization.

**High-pressure steam sterilization** is an effective method of sterilization but is the most difficult to do correctly (Gruendemann and Mangum 2001). It is generally the method of choice for sterilizing instruments and other items used in healthcare facilities. Where electricity is a problem, instruments can be sterilized in a nonelectric steam sterilizer using kerosene or other fuel as a heat source.

**Dry-heat sterilizers (ovens)** are good in humid climates but need a continuous supply of electricity, making them impractical in many remote (rural) areas. Furthermore, dry-heat sterilization, which requires use of higher temperatures, can be used only with glass or metal objects—it will melt other substances.

### **Standard Conditions for Heat Sterilization**

**Steam sterilization** (Gravity): Temperature should be 121°C (250°F); pressure should be 106 kPa (15 lbs/in<sup>2</sup>); 20 minutes for unwrapped items; 30 minutes for wrapped items. Or at a higher temperature of 132°C (270°F), pressure should be 30lbs/in<sup>2</sup>; 15 minutes for wrapped items.

Allow all items to dry before removing them from the sterilizer.

**Note**: Pressure settings (kPa or lbs/in<sup>2</sup>) may vary slightly depending on the sterilizer used. When possible, follow manufacturers' recommendations.

### Dry heat:

- 170°C (340°F) for 1 hour (total cycle time—placing instruments in oven, heating to 170°C, timing for 1 hour, and then cooling—is from 2–2.5 hours), or
- 160°C (320°F) for 2 hours (total cycle time is from 3–3.5 hours).

### Remember:

- Exposure time begins only after the sterilizer has reached the target temperature.
- Do not overload the sterilizer. (Leave at least 7.5 cm [3 inches] between the items and walls of sterilizer.) Overloading alters heat convection and increases the time required to sterilize.

Source: Perkins 1983.

Sterile instruments and other items should be used immediately unless they:

- were wrapped in a double layer of muslin, paper or other appropriate material prior to sterilization; or
- can be stored in a dry, sterile container with a tight-fitting lid.

The material used for wrapping instruments and other items must be porous enough to let steam through but tightly woven enough to protect against dust particles and microorganisms (see **Appendix G** for wrapping and packaging instructions). Wrapped sterile packs should remain sterile until some event causes the package or container to become contaminated. An event can be a tear or worn area in the wrapping, the package becoming wet or anything else that will allow microorganisms to enter the package or container.

Heat Sterilization for Prion diseases, such as Creutzfeldt-Jakob disease (CJD), are a group of **Prion Diseases** degenerative brain diseases that have received much attention during the past few years. They occur in animals (dogs, cows and primates) as well as humans and are rapidly fatal once symptoms develop. In humans, CJD remains rare with an incidence of less than 1 per million in the general population (Holman et al 1996). CJD poses a unique infection prevention problem because prions, which are protein-containing infectious agents, can survive recommended heat or high-pressure steam sterilization processes. In addition, chemical disinfectants, including sterilants such as glutaraldehydes and formaldehyde, are not strong enough to eliminate prion infectivity on contaminated instruments and other items. Therefore, surgical instruments and other critical devices contaminated with high-risk tissue (i.e., brain, spinal cord and eye tissue) from patients with known or suspected CJD require special treatment (Rutala and Weber 2001).

Recommendations for caring for patients with known or suspected CJD, as well as handling and processing contaminated instruments and other devices, include the following:

- Because the risk of transmission of prions from patients or noncritical items (e.g., dishes or bedpans) to health workers is low, only Standard Precautions are needed for patients with known or suspected CJD.
- During surgery, put a minimum number of instruments on the operative field and monitor which instruments were used. This reduces the number of instruments requiring special handling and processing.
- After surgery:
  - Avoid handling contaminated instruments.
  - Disposable items and personal protective equipment worn by the surgical team should be placed in a plastic bag and incinerated.

### Sterilization

**Note:** Do not soak contaminated instruments in dilute bleach (0.5% chlorine) solution or wash them.

- Following surgery, noncritical items such as the operating table, Mayo stand and other environmental surfaces can be decontaminated by wiping with a cloth soaked with 0.5% chlorine solution.
- Heat-resistant instruments and other devices should first be decontaminated by placing them in a gravity displacement sterilizer at 121°C (250°F) for 1 hour, or in a prevacuum sterilizer at 134°C (275°F) for 18 minutes.<sup>2</sup>
- After decontamination, clean and sterilize the instruments using the recommended processes (Chapter 10 and 11).
- Alternatively, after surgery, soak contaminated instruments and other devices in 1 *N* sodium hydroxide (NaOH) for 1 hour, then clean and sterilize them using recommended processes (Abrutyn, Goldman and Scheckler 1998; Fishman et al 2002).<sup>3, 4</sup>
- Biopsy tissue and surgical specimens should be placed in formalin for 48 hours, then in formic acid for 1 hour and, finally, back into fresh formalin for 48 hours (Abrutyn, Goldman and Scheckler 1998).

### STERILIZATION BY STEAM

**General Principles** Steam is an effective sterilant for two reasons. **First**, saturated steam is an extremely effective "carrier" of thermal energy. It is many times more effective in conveying this type of energy to the item than is hot (dry) air. In a kitchen, potatoes can be cooked in a few minutes in a steam pressure cooker while cooking may take an hour or more in a hot-air oven, even though the oven is operated at a much higher temperature. Steam, especially under pressure, carries thermal energy to the potatoes very quickly, while hot air does so very slowly. **Second**, steam is an effective sterilant because any resistant, protective outer layer of the microorganisms can be softened by the steam, allowing coagulation (similar to cooking an egg white) of the sensitive inner portions of the microorganism. Certain types of contaminants, however, especially greasy or oily materials, can protect microorganisms against the effects of steam, thus hindering the process of sterilization. This reemphasizes the need for **thorough cleaning** of objects before sterilization.

**Requirements** Steam sterilization requires four conditions: **adequate contact, sufficiently high temperature, correct time** and **sufficient moisture**. Although all are necessary for sterilization to take place, sterilization failures in clinics and hospitals are most often caused by lack of steam contact or failure to attain adequate temperature. All four conditions are discussed, in order of their importance in ensuring complete sterilization by steam, in **Appendix G**. This

<sup>&</sup>lt;sup>2</sup> Devices and instruments that are not heat-resistant or are difficult to clean should be incinerated.

<sup>&</sup>lt;sup>3</sup> WHO recommends that contaminated instruments be steam sterilized while they are still soaking in NaOH. This practice, however, is not recommended because of the additional risk of sterilizer damage and exposure of health workers to chemical toxicity. A warning regarding this practice has been posted on the CDC website (http://www.cdc.gov/ncidod/diseases/cjd/cjd\_inf\_ctrl\_qa.hun).

<sup>&</sup>lt;sup>4</sup> NaOH is caustic and after use must be neutralized before being disposed of by diluting with large amounts of tap water or addition of an acid, such as hydrochloric acid.

appendix also contains detailed instructions for operating steam sterilizers as well as instructions for wrapping and packing the items for sterilization.

- Advantages Most commonly used, effective method of sterilization.
  - Sterilization cycle time is shorter than with dry heat or chemical sterilants.

## **Disadvantages** • Requires a continuous source of heat (wood fuel, kerosene or electricity).

- Requires equipment (steam sterilizer), which must be expertly maintained to keep it in working condition.
- Requires strict adherence to time, temperature and pressure settings.
- Difficult to produce dry packs because breaks in procedure are common (e.g., not allowing items to dry before removing, especially in hot, humid climates).
- Repeated sterilization cycles can cause pitting and dulling of cutting edges of instruments (i.e., scissors).
- Plastic items cannot withstand high temperatures.

### Instructions (Steam Sterilizer)

**Note:** To help prevent dulling of sharp points and cutting edges, wrap the sharp edges and needle points in gauze before sterilizing. Repair (sharpen) or replace instruments as needed.

**Note**: Do not allow to boil dry. Steam should always be escaping from the pressure valve.

**STEP 1**: Decontaminate, clean and dry all instruments and other items to be sterilized.

**STEP 2**: All jointed instruments should be in the opened or unlocked position, while instruments composed of more than one part or sliding parts should be disassembled.

**STEP 3**: Instruments should not be held tightly together by rubber bands or any other means that will prevent steam contact with all surfaces.

**STEP 4**: Arrange packs in the chamber to allow free circulation and penetration of steam to all surfaces.

**STEP 5**: When using a steam sterilizer, it is best to wrap clean instruments or other clean items in a double thickness of muslin or newsprint. (Unwrapped instruments must be used immediately after removal from the sterilizer, unless kept in a covered, sterile container.)

If using a pressure cooker or kerosene-powered (nonelectric) gravity displacement steam sterilizer, bring the water to a boil and let steam escape from the **pressure valve**; then turn down heat, but keep steam coming out of the pressure valve.

**STEP 6**: Sterilize at 121°C (250°F) for **30 minutes** for wrapped items, **20 minutes** for unwrapped items; time with a clock.

**Note:** Do not store trays or packs until they reach room temperature. This usually takes about an hour. **STEP 7**: Wait 20 to 30 minutes (or until the pressure gauge reads zero) to permit the sterilizer to cool sufficiently. Then open the lid or door to allow steam to escape. Allow instrument packs to dry completely before removal, which may take up to 30 minutes. (Wet packs act like a wick drawing in bacteria, viruses and fungi from the environment.) Wrapped instrument packs are considered unacceptable if there are water droplets or visible moisture on the package exterior when they are removed from the steam sterilizer chamber. If using rigid containers (e.g., drums), close the gaskets.

**STEP 8**: To prevent condensation, when removing the packs from the chamber, place sterile trays and packs on a surface padded with paper or fabric.

**STEP 9**: After sterilizing, items wrapped in cloth or paper are considered sterile as long as the pack remains clean, dry (including no water stains) and intact. Unwrapped items must be used immediately or stored in covered, sterile containers.

Ideally, a steam sterilizer log should be kept, noting time:

- heat begun,
- correct temperature and pressure achieved,
- heat turned down, and
- heat turned off.

Keeping a log can help ensure that the required amount of time will be observed, even when multiple, new or hurried workers are responsible for overseeing sterilization.

### STERILIZATION BY DRY HEAT

When available, dry heat is a practical way to sterilize needles and other instruments. A convection oven with an insulated stainless steel chamber and perforated shelving to allow the circulation of hot air is recommended, but dry-heat sterilization can be achieved with a simple oven as long as a thermometer is used to verify the temperature inside the oven.

### Effectiveness

**Remember**: Just as with steam sterilization, thorough cleaning of the object prior to dry heat sterilization is critical. If an instrument is not properly cleaned, sterilization cannot be ensured, regardless of how long the instrument is heated. Dry-heat sterilization is accomplished by thermal (heat) conduction. Initially, heat is absorbed by the exterior surface of an item and then passed to the next layer. Eventually, the entire object reaches the temperature needed for sterilization. Death of microorganisms occurs with dry heat by a process of slow destruction of protein. Dry-heat sterilization takes longer than steam sterilization, because the moisture in the steam sterilization process significantly speeds up the penetration of heat and shortens the time needed to kill microorganisms.

- Advantages Effective method, as dry heat by conduction reaches all surfaces of instruments, even for instruments that cannot be disassembled.
  - Protective of sharps or instruments with a cutting edge (fewer problems with dulling of cutting edges).
  - Leaves no chemical residue.
  - Eliminates "wet pack" problems in humid climates.
- Plastic and rubber items cannot be dry-heat sterilized because temperatures used (160–170°C) are too high for these materials.
  - Dry heat penetrates materials slowly and unevenly.
  - Requires oven and continuous source of electricity.

### Instructions (Dry Heat Oven)

**Note:** When using dry heat to sterilize instruments wrapped in cloth, be sure that temperature does not exceed  $170^{\circ}$ C/340°F.

**Note**: Use dry heat only for items that can withstand a temperature of 170°C (340°F) (Perkins 1983).

**Note:** Needles and other instruments with cutting edges should be sterilized at lower temperatures (160°C [320°F]), because higher temperatures can destroy the sharpness of cutting edges (Perkins 1983). To ensure correct operation, consult specific operating instructions supplied by the oven's manufacturer.

**STEP 1**: Decontaminate, clean and dry all instruments and other items to be sterilized.

**STEP 2**: If desired, wrap instruments in aluminum foil or place in a metal container with a tight-fitting, closed lid. Wrapping helps prevent recontamination prior to use. Hypodermic or suture needles should be placed in glass tubes with cotton stoppers.

**STEP 3**: Place loose (unwrapped) instruments in metal containers or on trays in the oven and heat to desired temperature.

**STEP 4**: After the desired temperature is reached, begin timing. The following temperature/time ratios are recommended (APIC 2002):

| 170°C (340°F) | 60 minutes  |
|---------------|-------------|
| 160°C (320°F) | 120 minutes |
| 150°C (300°F) | 150 minutes |
| 140°C (285°F) | 180 minutes |
| 121°C (250°F) | overnight   |

Depending on the temperature selected, the total cycle time (preheating, sterilization time and cool down) will range from about 2.5 hours at 170°C to more than 8 hours at 121°C.

**STEP 5**: After cooling, remove packs and/or metal containers and store. Loose items should be removed with sterile forceps/pickups and used immediately or placed in a sterile container with a tight-fitting lid.

### CHEMICAL STERILIZATION

**Note**: Chemical sterilization of hypodermic

needles and syringes is not recommended, because chemical residues, which may remain even after repeated rinsing with **boiled** water, may interfere with the action of medications being injected.

**Note**: Because boiling and steaming does not reliably inactivate all endospores, rinsing with boiled water can contaminate **sterile** instruments. It is, however, the only acceptable alternative if sterile water is not available.

**Remember**: Do not dilute formaldehyde with chlorinated water, because a dangerous gas (bischloromethyl-ether) is produced.

### Advantages

An alternative to high-pressure steam or dry-heat sterilization is chemical sterilization (often called "cold sterilization"). If objects need to be sterilized, but using high-pressure steam or dry-heat sterilization would damage them or equipment is not available (or operational), they can be chemically sterilized.

Some high-level disinfectants will kill endospores after prolonged (10–24 hour) exposure. Common disinfectants that can be used for chemical sterilization include glutaraldehydes and formaldehyde. Sterilization takes place by soaking for at least 10 hours in 2–4% glutaraldehyde solution or at least 24 hours in 8% formaldehyde. Glutaraldehydes, such as Cidex<sup>®</sup>, are often in short supply and very expensive, but they are the only practical sterilants for some instruments, such as laparoscopes, which cannot be heated. Both glutaraldehydes and formaldehyde require special handling and leave a residue on treated instruments; therefore, rinsing with **sterile** water is essential if the item must be kept sterile. Also, if not rinsed off, this residue can interfere (cause sticking) with the sliding parts of the laparoscope and cloud the lens.

Although formaldehyde is less expensive than glutaraldehydes, it is also more irritating to the skin, eyes and respiratory tract and is classified as a potential carcinogen (Rutala 1996). When using either glutaraldehydes or formaldehyde, wear gloves to avoid skin contact, wear eyewear to protect from splashes, limit exposure time and use both chemicals only in wellventilated areas (Clark 1983).

As items are unwrapped after chemical sterilization, they should be transported and stored in a covered, sterile container. (**Table 12-1** provides guidelines for preparing and using glutaraldehydes and formaldehyde solutions.)

- Glutaraldehydes and formaldehyde solutions are not readily inactivated by organic materials.
  - Both can be used for items that will not tolerate heat sterilization such as laparoscopes.
- Formaldehyde solutions can be used for up to 14 days (replace sooner if cloudy); some glutaraldehydes can be used for up to 28 days. (Check the manufacturers' instructions and see also **Appendix F**).<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> Although manufacturers provide guidelines for dilution and for how long a solution can be used, many of their claims have not been validated (Gurevich, Yannelli and Cunha 1990). Chemical strip tests can be used to determine the effectiveness of a solution. If these are not available or practical, use the solution only for the minimum recommended time and change it if it is diluted by wet instruments or is visibly cloudy.

| Disadvantages  | • Glutaraldehydes and formaldehyde are chemicals that cause skin irritation; therefore, all equipment soaked in either solution must be thoroughly rinsed with sterile water after soaking.   |  |
|--|---|--|
|  | • Because glutaraldehydes work best at room temperature, chemical sterilization cannot be assured in cold environments (temperatures less than 20°C/68°F), even with prolonged soaking.   |  |
|  | • Glutaraldehydes are expensive.  |  |
|  | • Vapors from formaldehyde (classified as a potential carcinogen), and to a lesser degree glutaraldehydes, are irritating to the skin, eyes and respiratory tract. Wear gloves and eyewear, limit exposure time and use both chemicals only in well-ventilated areas. |  |
|  | • Formaldehyde cannot be mixed with chlorine or chlorinated water because a dangerous gas (bis-chloromethyl-ether) is produced.   |  |
| Instructions<br>(Chemical Sterilization)   | <b>STEP 1</b> : Decontaminate, clean and dry all instruments and other items to be sterilized.  |  |
|  | <b>STEP 2</b> : Completely submerge items in a clean container filled with the chemical solution and place the lid on the container.  |  |
|  | <b>STEP 3</b> : Allow items to soak:  |  |
|  | • 10 hours in a glutaraldehyde (check specific product instructions), or  |  |
|  | • at least 24 hours in 8% formaldehyde.   |  |
| <b>Note</b> : Ideally, <b>three</b><br>separate (sequential) rinse<br>containers should be used. | <b>STEP 4</b> : Remove objects from the solution with sterile forceps; rinse all surfaces three times in sterile water and air dry.   |  |
|  | <b>STEP 5</b> : Store objects in a sterile container with a tight-fitting lid if they will not be used immediately.   |  |
| MONITORING STERILI   | ZATION PROCEDURES   |  |
|  |   |  |
|  |   |  |

**Biological Indicators** 

**Remember**: Different sterilization processes have different monitoring requirements.

Sterilization procedures can be monitored routinely using a combination of biological, chemical and mechanical indicators as parameters.

Monitoring the sterilization process with reliable biological indicators at regular intervals is strongly recommended. Measurements should be performed with a biological indicator that employs spores of established resistance in a known population. The biological indicator types and minimum recommended intervals should be:

- Steam sterilizers: Bacillus stearothermophilus, weekly and as needed •
- Dry-heat sterilizers: Bacillus subtilis, weekly and as needed •

| Chemical Indicators   | Chemical indicators include indicator tape or labels, which monitor time, temperature and pressure for steam sterilization, and time and temperature for dry-heat sterilization. These indicators should be used on the inside and outside of each package or container.   |
|---|--|
|   | <b>External indicators</b> are used to verify that items have been exposed to the correct conditions of the sterilization process and that the specific pack has been sterilized. <b>Internal indicators</b> are placed inside a pack or container in the area most difficult for the sterilization agent to reach (i.e., the middle of a linen pack). This is the indicator that tells if the item has been sterilized.   |
|   | Chemical indicators, such as heat sensitive tape or glass vials containing<br>pellets that melt at certain temperatures for a given time, do not guarantee<br>that sterilization has been achieved. They do, however, indicate whether<br>mechanical or procedural problems in the sterilization process have occurred.  |
| Mechanical Indicators   | Mechanical indicators for sterilizers provide a visible record of the time,<br>temperature and pressure for that sterilization cycle. This is usually a printout<br>or graph from the sterilizer, or it can be a log of time, temperature and<br>pressure kept by the person responsible for the sterilization process that day.   |
| STORAGE   |  |
|   | All sterile items should be stored in an area and manner whereby the packs or<br>containers will be protected from dust, dirt, moisture, animals and insects.<br>This storage area is best located next to or connected to where sterilization<br>occurs, in a separate enclosed area with limited access that is used just to<br>store sterile and clean patient care supplies. In smaller facilities, this area<br>may be just a room off the Central Supply Department or in the operating<br>unit. |
|   | • Keep the storage area clean, dry, dust-free and lint-free.   |
|   | • Control temperature and humidity (approximate temperature 24°C and relative humidity <70%) when possible.  |
|   | • Packs and containers with sterile (or high-level disinfected) items should be stored 20–25 cm (8–10 inches) off the floor, 45–50 cm (18–20 inches) from the ceiling and 15–20 cm (6–8 inches) from an outside wall.  |
|   | • Do not use cardboard boxes for storage. Cardboard boxes shed dust and debris and may harbor insects.   |
| <b>Note</b> : Sterile packs will not<br>remain sterile unless<br>properly stored. | <ul> <li>Date and rotate the supplies (first in/first out). This process serves as a reminder, but does not guarantee sterility of the packs.</li> </ul>   |
|   | • Distribute sterile and high-level disinfected items from this area.  |
| Shelf Life  | The shelf life of an item (i.e., how long items can be considered sterile) after sterilization is event-related. The item remains sterile until something causes   |

the package or container to become contaminated—time elapsed since sterilization is not the determining factor. An event can be a tear or worn area in the wrapping, the package becoming wet or anything else that will enable microorganisms to enter the package or container. These events can occur at any time.

Therefore the shelf life of sterilization depends on the following factors:

- Quality of the wrapper or container
- Number of times a package is handled before use
- Number of people who have handled the package
- Whether the package is stored on open or closed shelves
- Condition of storage area (e.g., humidity and cleanliness)
- Use of plastic dust covers and method of sealing (AORN 1992)

Most packages are contaminated as a direct result of frequent or improper handling or storage. To make sure items remain sterile until you need them:

- prevent events that can contaminate sterile packs, and
- protect them by placing them in plastic covers (bags).

Before using any sterile item, look at the package to make sure the wrapper is intact, the seal unbroken and is clean and dry (as well as having no water stains), then you can be reasonably sure it is sterile regardless of when it was sterilized (Gruendemann and Mangum 2001).

In some healthcare facilities where replacement of supplies is limited and the cloth used for wrapping is of poor quality, time as a limiting factor also serves as a safety margin. If plastic covers (bags) are unavailable for the sterilized items, limiting the shelf life to a specific length of time (e.g., 1 month) may be a reasonable decision as long as the pack remains dry and intact.

### **OTHER STERILIZATION METHODS**

**Gas Sterilization** The use of **formaldehyde gas** for killing microorganisms was practiced before the turn of the century. One of the first uses of formaldehyde gas was to fumigate rooms, a practice long since shown to be ineffective and unnecessary (Schmidt 1899). There are, however, automatic, low-temperature steam formaldehyde sterilizers that are effective and can be used to process heat-sensitive instruments and plastic items. As mentioned previously, because formaldehyde vapors are irritating to the skin, eyes and respiratory tract, the use of formaldehyde in this form should be limited.

In the United States and several other countries, **ethylene oxide (ETO)** gas is used for sterilization of heat- and moisture-sensitive surgical instruments, such as plastic devices and delicate instruments. Sterilization using ETO, however, is a more complicated (requires a 2-hour exposure time and a long aeration period) and expensive process than either steam or dry-heat sterilization.<sup>6</sup> In addition, it requires sophisticated equipment and skilled staff specially trained for its safe use, making it impractical for use in many countries (Gruendemann and Mangum 2001).

ETO is hazardous to healthcare workers, patients and the environment. Because ETO is moderately toxic when inhaled, regular exposure to low levels (greater than 1 part per million) may produce harmful effects in humans. Moreover, the gas is irritating to the eyes and mucous membranes, and residual ETO on instruments can cause skin injuries and inflammatory reactions in patients. Finally, because ethylene oxide, a toxic product, is classified as a potential carcinogen as well as a mutagen, disposing of it is difficult (Gruendemann and Mangum 2001).

Ultraviolet Light Sterilization Ultraviolet (UV) light has been used to help disinfect the air for more than 50 years (Morris 1972). For example, UV irradiation can interrupt transmission of airborne infections in enclosed indoor environments where living conditions are poor and people are crowded together. Because UV irradiation has very limited energy, UV light does **not** penetrate dust, mucous or water. Therefore, despite manufacturers' claims, it **cannot** be used to sterilize water. Although in theory intense UV light can be both bactericidal and viricidal, in practice only limited disinfection of instruments can be achieved. This is because the UV rays can kill only those microorganisms that are struck directly by UV light beams. For surfaces that cannot be reached by the UV rays (e.g., inside the barrel of a needle or laparoscope), any microorganisms present will not be killed (Gruendemann and Mangum 2001).

Other disadvantages of UV:

- It requires a reliable source of electricity.
- It is not effective in areas of high relative humidity.
- UV bulbs require frequent cleaning to remain effective.
- Exposure to UV rays can burn the skin and eyes.

As a consequence, UV irradiation is neither a practical nor effective method in most situations (Riley and Nardell 1989).

<sup>&</sup>lt;sup>6</sup> Items that are sterilized by ETO need to be aerated (to the outside), so that the residual ETO gas can diffuse out of the packages and items. This can take long periods of time leading to complete cycle times of 24 hours or more (Steelman 1992).

- Paracetic acid (peroxyacetic acid). The acid is rapidly effective against all microorganisms, organic matter does not diminish its activity and it decomposes into safe products. When diluted, it is very unstable and must be used with a specially designed automatic sterilizer (APIC 2002). It is usually used for sterilizing different types of endoscopes and other heat-sensitive instruments.
  - **Paraformaldehyde**. This solid polymer of formaldehyde may be vaporized by dry heat in an enclosed area to sterilize objects (Taylor, Barbeito and Gremillion 1969). This technique, called "self-sterilization" (Tulis 1973), may be well suited for sterilizing endoscopes and other heat-sensitive instruments.
  - Gas plasma sterilization (hydrogen peroxide based). This method can sterilize items in less than 1 hour and has no harmful by products. It does not penetrate well, however, and cannot be used on paper or linen. A specialized sterilizer is required for performing gas plasma sterilization (Taurasi 1997).

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