Practical Application of Basic Sterilization Principles

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To many, the world of sterilization is fraught with confusion, apprehension and distrust! Comments such as "But there's so much you have to know" or "I'll never be able to learn all of that!" frequently invade the thoughts of individuals faced with the responsibility of insuring that supplies are sterile and safe for use. However mysterious it seems at first, the world of sterilization is not quite as formidable as it appears. Once a few basic principles are understood and observed, the process of sterilization can be looked upon as a friendly adjunct to the successful treatment of the patient and not as a "Chinese puzzle" existing only to confuse the perfusionist!

Sterilization is defined as the total destruction of all microbial life, including spores. In addition, successful sterilization must include an absence of remaining toxic residue and the absence of damage to the material sterilized. Since organisms must be able to reproduce in order to stay alive, organisms are considered dead when there is an irreversible cessation of the vital processes which are essential for growth and reproduction.[1] This change may occur immediately upon contact or may be a slower process, depending upon the method of sterilization employed. Research has shown that organisms die in a logarithimic pattern, that is, the rate of death is directly proportional to the number of organisms present at any given time. For example, based on the assumption that 1 million bacteria per milliliter of solution are subjected to a sterilizing force, 90% of the organisms are killed per minute of exposure as demonstrated below:

1,000,000 live organisms, 90% die 1st minute, leaving 100,000 organisms
100,000 live organisms, 90% die 2nd minute, leaving 10,000 organisms
10,000 live organisms, 90% die 3rd minute, leaving 1,000 organisms

This process continues until at the end of 10 minutes, there are 0.0001 organisms. Theoretically, as seen from the above pattern, *pure* sterility is never attained.[2] Practically speaking, however, a point arrives at which time the remaining percentage is so small that the condition of sterility is recognized. Requisites which must be met to insure the destruction of sufficient organisms to arrive at a state of sterility have been determined through research and are the basics from which current sterilization parameters are founded.

Of the various methods of sterilization available today, the three most generally accepted methods are steam under pressure, ethylene oxide gas and gamma irradiation. Dry heat sterilization is decreasing in popularity and is most likely not indicated for any materials the perfusionist uses. Chemical sterilization (more commonly known as chemical disinfection) is now a possibility with the availability of

the glutaraldehydes such as Cidex and Sonacide; however, because of the many variables involved, insurance that a state of sterility has been attained remains suspect. For that reason, soaking of items should be discouraged and used only as a last resort after all other possibilities for sterilization have been exhausted.

The following paragraphs present a brief discussion of each of these three methods of sterilization.

Steam Under Pressure

Because of the availability, speed, economy and reliability of steam autoclaving, it is still the most widely used and accepted method of sterilization. The major disadvantage is the destruction or deterioration of certain materials unable to withstand excessive heat or moisture. Since moisture is the sterilizing agent, the effectiveness of steam sterilization is dependent upon adequate penetration of steam to all surfaces of all items being sterilized. Once this is accomplished, sufficient exposure time at the required temperature must be insured to complete the cycle. Pressure is important *only* that it allows the temperature to reach the proper elevation, but does in no way affect the penetration of steam or contribute otherwise to the sterilization process. Temperature and time are variables and as the temperature is increased, the time may be proportionately decreased.

Currently, the most commonly used autoclaves are the High-vacuum type which are safer and faster than the older downward-displacement or gravity-type sterilizers. By creating a vacuum, the cool air is drawn out before the steam is admitted, thus allowing a more rapid, evenly distributed flow of steam. The "Flash" sterilizer is used for rapid sterilization of unwrapped materials and operates at 270-275 degrees F (130 degrees C) at 27-30 pounds pressure, with the total cycle being completed in three minutes. The addition of a porous material such as a sponge, towel or wrapper increases the required exposure time so the total cycle becomes ten minutes. Certain additional articles may require an extended exposure time but specific sterilization instructions usually indicate this. The other type of high-vacuum sterilizer is designed for sterilizing packs and wrapped goods and includes an exhaust and drying cycle. The temperature is the same (some may operate only at 250 degrees), but because of the additional time needed for steam to penetrate packs, exposure time is usually 4-10 minutes or more. Total cycle time can be as long as 40-60 minutes, depending upon the time required for adequate drying of items to take place. Older gravity-type autoclaves which operate at a temperature of 250 degrees F (121 degrees C) require as much as 15-45 minutes exposure time, therefore, the total cycle time is increased considerably to allow for exhaust and adequate drying of articles. There are numerous references available which outline specific load-time requirements for all types of sterilizers and materials so a detailed listing will not be included here.

Ethylene Oxide Sterilization

Ethylene Oxide or "gas" has been a most welcome addition to the field of sterilization. Because it can be used for most items adversely affected by steam autoclaving, it is of particular importance to the perfusionist, since most supplies used by the extracorporeal specialist are not steam sterilizable. The major disadvantages of EO sterilization relate to the toxic properties of the gas, therefore, strict

observance of safety precautions is imperative to avoid serious injury to the patient and to the user. Toxic residues, including ethylene glycol and chlorohydrin which can form as a result of chemical changes during the sterilization process can remain on processed items, thus posing additional problems. Acceptable limits of these residues are available for reference.[3]

There are four components of EO sterilization which must be in proper relationship before sterilization can be assured. Gas concentration may be varied from the minimum of 450 mg/liter to 1000 mg/liter. As concentrations increase, exposure time is proportionately decreased, however, concentrations above 1000 mg/liter do not appreciably decrease exposure times any further.[4] Routine temperatures fall within 120 degrees F to 140 degrees F (49 degrees to 60 degrees C) but may be kept as low as 70 degrees F for heat-sensitive materials. Humidity is required and is most effective between 25-60%. Since the time factor can be adjusted in relationship to temperature or gas concentrations, routine sterilization can usually be accomplished within 3-6 months, however, as long as 14 hours may be required if gas concentration and/or temperature is very low. Following the sterilization cycle, and depending upon the materials, articles must be aerated from 12 hours to 12 days to allow all toxic effects of the gas to dissipate. The use of an aerator with a controlled temperature of 50-60 degrees C greatly accelerates the desorption of residuals.[5] Prescribed aeration times must be conscientiously and knowledgeably followed to avoid serious injury and/or complications for the patient. Because of the length of time required to complete the total process, careful planning and anticipation of required needs is essential.

Gamma Irradiation

The latest addition to the armamentarium of sterilization is the use of X-rays as a type of ionizing sterilization. Presently limited in its availability because of cost and equipment requirement, it is expected that irradiation will become increasingly more available in the future. Although gamma irradiation is not suitable for all types of materials, it is being used by some of the larger manufacturing companies for routine disposable hospital equipment, as well as specialized surgical implants and prostheses. Items processed by irradiation are clearly marked and frequently include the method of processing used. Because of the existing confusion as to the advisability of reprocessing items with ethylene oxide, most manufacturers recommend that products be returned to the company if reprocessing becomes necessary. Readers should be alert to further developments in reprocessing as more information becomes available.

To help clarify some of the issues and questions pertaining to the various methods of sterilization, it will be helpful to review the basic principles involved, all of which pertain to any method of sterilization used.

Principle I: All items to be used for any surgical procedure must be sterilized prior to use.

Never "assume" that an item is sterile. If packaged by the manufacturer, carefully check the package for the word "STERILE." Many items will say "Sterilized by EO" or by "Gamma Rays" or whatever is appropriate. Items so designated must be considered unsterile and must be processed before use. All sterile packages must be carefully examined for pinpoint holes or tears in the wrapper, for any evidence of

moisture or deterioration, and for expiration date. Care must be used in transferring items from the package to the sterile field to insure that inadvertent contamination does not occur.

Principle II: Items must be mechanically cleansed before attempting the sterilization process.

Gross soilage such as blood, mucus, pus, tissue, oil or greasy film of any kind, sticky-tape or any other types of gross contamination must be mechanically removed. Since most methods of sterilization will not penetrate these proteins or inert substances, grossly dirty items may not be free from organisms following the sterilization process. Also, since organisms die in a logarithmic order, the more contaminated an item is, the longer the required sterilization time will be.

Principle III: Items must be packaged correctly and according to guidelines provided for the various methods of sterilization used.

Items must not exceed the recommended size and/or weight (12″-12″-20″ or 10-12 pounds) and must be packaged to insure penetration of the sterilizing agent. Autoclaves must be loaded in such a manner as to insure complete penetration of steam or EO to surfaces of all packages. Cloth wrappers must be of the prescribed thread count and paper or synthetic packages must allow adequate penetration without trapping air or gas and without allowing invasion of contaminates. Wrappers such as nylon, foil, saran and PVC film should not be used for EO sterilization.[6] Outer wraps must be of sufficient strength to withstand post-sterilization handling and must be applied in such a manner that sterility of the item can be maintained while opening. Since some packages are not recommended for certain types of sterilization, careful selection of packaging materials must be employed to insure the appropriateness of materials used.

Principle IV: Biological testing and other safeguards must be employed and used according to recommended standards to insure the safety and effectiveness of the sterilizing process.

Spore tests should be used daily in the first cycle of the steam autoclave, and with each load when using EO sterilization. Temperature graphs must be maintained for each load, and indicators which change only when sterilizing conditions have been met are recommended. Sterilizer tape does not indicate sterility but is a helpful method of identifying whether or not a package has been exposed to the sterilization process.

Principle V: Following sterilization, items must be handled, stored, and opened according to established principles of aseptic technique.

Packages must be completely dry before being removed from the autoclave, otherwise immediate contamination will occur. Packages should be stored in a segregated area where only sterile items are placed, and should be maintained in a closed, dry, vermin-free area. Items dropped on the floor must be considered contaminated and immediately removed for the sterile package and sterile packages should only be handled with clean hands. When opening items, unsterile edges of packages must not come in contact with the article, and it is recommended that most articles be lifted out of the package by a gowned and gloved person rather than "throwing" the article on the sterile field.

Principle VI: If any doubt exists as to the sterility of an item, it must be considered unsterile.

Sterility is like pregnancy, it either exists or it doesn't . . . there is no in between! Items found where sterile items are usually not kept, illegible dates, packages that feel damp, wrappers with questionable tears, packages discolored or showing evidence of deterioration are all examples of questionable sterility and must be discarded.

The preceding principles and discussion should provide the extracorporeal specialist a basic foundation from which to build a practical and working knowledge of the principles of sterilization and sterilization methods. The many synthetic products and special items currently on the market have made a knowledge of sterilization, including the specific management of certain materials, essential to the clinical perfusionist. Although it may sound like an overwhelming task, an understanding of sterilization is possible if responsible individuals acquire a basic knowledge of principles and techniques, apply a common-sense approach, and develop a questioning mind. As the great philosopher Bacon so aptly stated, "If a man will begin with certainties he shall end in doubts; but if he will be content to begin with doubts he shall end in certainties."

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RECOMMENDED READING

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