Sterilization technology has never been as challenging as in the current millennium. New methods of sterilization and disinfection have been introduced or have been under development. Various processes have different sterilization characteristics and different effects on the medical device to be processed. Yet we have less time and staff than ever before to make educated decisions. The acquisition and equipment and devices requires a careful study of efficacy, regulatory compliance, as well as patient and worker safety. Standardization of medical devices and procedures is a solution to the future of sterilization.
Central Sterile Management

The State of Sterilization Today

Hospital administrators are evaluating devices and methodology based on cost, efficiency and a return on investment. The health care community is under pressure as it is faced with lower operating budgets, reduced staff and an increasing volume of patients. The resistance of certain microorganisms to traditional methods of decontamination is frightening, especially when prions are concerned. Resistant microbes, including spores, are hard to kill and present challenges to instrument processing personnel who are under pressure to rapidly turn the instrument sets. Sterilization practices, such as gravity displacement flash and EO gas, are being examined or eliminated—the former for the risk of nonsterile loads due to reduced exposure time and the inherent wet loads associated with reduced dry time, and the latter due to long processing and aeration time, toxicity to hospital workers attributable to possible carcinogenic exposure and environmental effects such as destruction to the ozone layer.

We have a choice between various methods including steam sterilization, alkulation and oxidation. Steam, the oldest and most commonly used method, has advantages which include speed, low cost and low environmental impact. However, some devices are heat or moisture sensitive and may corrode after repeated exposure to steam. Therefore other methods need to be utilized. Alkalation is one method of cold sterilization. EO and glutaraldehyde function by interfering with the organism’s reproduction and other critical functions. Many of the newest of sterilization methods and those under development involve the use of oxidizing agents. These include hydrogen peroxide, peracetic acid and ozone. They react by damaging the cell wall and affecting the genetic material of the organism.

According to AAMI standard ST33, sterilization is defined as a validated process used to render a product free of all forms of viable microorganisms. It is noted that the nature of microbial death is an exponential function and while this probability can be reduced to a very low number, it can never be reduced to zero. Although the basic principles of sterilization are the same, today’s instrumenta-
tion is more complex and sophisticated, requiring special cleaning, handling and sterilization procedures. Some devices are compatible with current methods and some are not. It is up to us to be informed and to make proper purchasing decisions based on need and efficacy.

The goal of sterilization is to produce sterile products that improve patient outcome. It is fundamental to safe patient care. Without sterilization, modern surgical procedures would be impossible. Minimally invasive surgical devices, such as endoscopes, while providing a substantial improvement over invasive surgical instruments, are hard to clean, decontaminate and sterilize. Some are heat and temperature sensitive and require special processing. Furthermore, endoscopes are expensive to replace and maintain and require protection in handling. For these reasons, it is important to choose the correct sterilization and packaging solution as we move forward in the new millennium. One must consider added value such as instrument protection and efficacy in addition to cost factors.

The selection process for new sterilization devices places added demands on the individual in CS and the OR who is responsible for sterilization process and purchasing decisions. There is no one method for sterile processing and the objectives to be met are complex. The item must be protected and sterile until point of use to ensure positive patient outcomes. The sterilization process must be quick, cost effective and rigorous with kill at half cycles at six logs. The packaging must be durable for transport, have excellent sterilant penetration and protect the contents until point of use even with multiple handling events. Event related sterility has become the standard for shelf life. A specific date is no longer required. Hospitals now can establish written policies based on their internal practices. Furthermore, process and load monitoring are crucial to validate that an item has been fully processed/sterilized and presents no risk to the patient. Marginal methods must be identified. There are many items that cannot be sterilized by heat or steam and must be processed in low-temperature sterilizers. Training, in-service, education and now certification contribute to the professional knowledge base now are necessary for staff competencies in the sterilization arena.

All photos courtesy of Case Medical, Inc.
Proper Processing Every Time

The sterilization or disinfection of medical devices is far from simple. It requires a base of knowledge and proper decision making on the part of the staff. Modern complex instrumentation requires special cleaning, decontamination and sterilization. The resistance of microorganisms to destructive agents such as heat, chemicals and ionizing radiation forms the basis of all sterilization. Successful sterilization requires careful steps, which must be followed to ensure a positive outcome. Any break in the procedure can result in contamination of the product and harm to the patient or healthcare worker. That is why it is necessary to standardize practices and have clearly defined steps when processing surgical instruments and medical devices.

1) Establish standardized policies and procedures for processing. This will help to control the outcome.
2) Always clean and decontaminate before sterilization. Don’t wait. Use solutions, such as enzymatic pre-soak to keep instruments moist and reduce the accumulation of bio-burden by rinsing or cleaning near the OR.
3) Organize and plan your instrument sets for processing. Standardize sets. This can save time in reprocessing and increase productivity.
4) Be sure the sterilizer is properly functioning and not overloaded. Always validate.
5) Importantly, be sure your sterilization method is appropriate for the device. The packaging you use should enhance the sterilization process. Check with the manufacturer to ensure that the wrap or container has been validated for the particular method. Ask for the validation studies and 510k.

Proper processing takes time. Organization, standardization and informed decision-making can save time while reducing the risk of infection to the patient. As new methods of sterilization are implemented and introduced, it is important for us to remain informed of new technology. Currently, many healthcare facilities are standardizing and implementing computerized tracking programs. Others are considering centralizing sterile processing or contracting with independent off-site centers for their processing needs. Meanwhile, new handling systems such as bar code tracking, robotic transport and case cart systems are being implemented to control and move product. Sealed containers and medical grade disposable wrap are replacing linen in most healthcare facilities. Looking at future trends, those with 510k, event-related sterility validation and efficacy in various sterilization systems would be the standard. Sterilization indicators having multiple parameters with rapid readout now are available. As sterilization of cannulated devices increases, instant read indicators inside of lumens would become the indicator of choice.

Standardization Goes Global

Modern medicine and patient care is dependent on the oversight of various agencies and vigilance on our part that the procedure is effective. Regulatory agencies, such as JCAHO, FDA and OSHA provide oversight functions. Agencies such as AORN and AAMI develop standards and recommended practices for the use and the monitoring of sterilization processes. In addition, there is greater awareness on a global level as to the importance of shared knowledge and universal standards, as well as standardization of medical devices. Europe, with established DIN sizes, ISO quality certification and CE mark, has led the way in defining validation procedures and standards.

Global standardization is not far behind. Companies in the United States that have complied with QSR in the United States and European standards have greater acceptance in the universal marketplace. Instruments and other items to be sterilized must be packaged so that their sterility is maintained until point of use. The packaging material must allow for sterilant contact with each item during the sterilization process and protect the items from contamination during storage and transport. Adequate time must be allocated to properly sterilize loads—in particular those made of plastic materials, or with hinged or lumened devices. Gravity displacement flash is already banned in other countries, including Australia, Canada, Europe and South America. We will follow suit before long, using rapid pre-vacuum steam and other methods with new dynamic air removal systems instead of flash. Unwrapped transport of sterile items will be a thing of the past. We already have various packaging materials available from wrap; peel pouches to rigid sealed containers. It is important to check with the device manufacturer as to efficacy and compatibility. Materials such as aluminum have exceptional thermoconductivity. To date only one sealed container, SteriTite by Case Medical, has been fully validated for steam and gas plasma sterilization. To ensure that instruments and supplies are sterile at point of use, it is essential to monitor the process. Applying universal procedures and standards in instrument processing can only enhance our level of service to our patients and make our lives safer.

Marcia Frieze, MS is CEO of Case Medical located in Richfield, NJ. She has been instrumental in developing the company’s line of modular instrument trays and the SteriTite, universal sealed container system. Marcia has also developed clinical seminars and training programs and has articles published related to infection control, sterilization and packaging.

References Available Upon Request