Worldwide, healthcare professionals are looking for products and solutions that offer better outcomes. They are looking for information that can provide them with knowledge needed to make informed buying decisions—information they can trust from responsible suppliers. Competition can bring out the best solutions, excellent products with technological breakthroughs, but if misused, it can bring out the worst in people. This is true if it is done without integrity or concern for the public good.

Many healthcare facilities have incorporated the latest surgical innovations, robotics, endoscopic procedures, e-business solutions, inventory tracking systems and acquisition of state-of-the-art medical devices. Products are being evaluated based on cost, safety and the effect on the environment. Some countries are establishing their green credentials. African healthcare workers are concerned about environmentally correct medical supplies; those that are biodegradable and reusable are particularly in demand. In Europe,
especially Great Britain, cleaning, disinfection and sterilization have taken on new meaning and importance in response to recent outbreaks of Mad Cow, and Hoof and Mouth Disease. There are standard operating procedures for decontamination and sterilization of surgical instruments exposed to prions. This includes extended processing time as well as incineration, as no one truly knows whether prions can be killed by standard methods of decontamination and sterilization.

As the healthcare community struggles with resistant microbes, it must also overcome a shortage of staff and a decrease in time to fully process and terminally sterilize medical devices. It is time to present sustainable solutions: products and solutions that are truly effective, backed with validation testing and written documentation.

Around the globe, healthcare workers are focused on infection control, education, certification and professionalism. They turn to the industry to supply information and product knowledge. Can they trust their suppliers? Since the recent corporate scandals, involving Enron, Worldcom and lapses in business ethics, corporations—including healthcare facilities along with medical device manufacturers and suppliers—need to commit to the pursuit of corporate ethics and social responsibility. According to one dean of a major business school, “You may not be able to change character…but you can teach people to recognize an ethical problem when it arises.”

Most of us, irrespective of geography, have the same goals in mind when processing and sterilizing medical devices for surgery. First is safe patient outcome. Then, there are other goals that contribute to a better work environment. These include ways to increase productivity and avoid unnecessary duplication, create a supportive work environment and reduce stress, and improve communication with the other departments in the healthcare community. Next are goals related to personal and professional growth, such as establishing a body of knowledge, education and certification.

Sterile processing is a service department of the hospital. The technicians providing this service rarely see
the ultimate consumer they serve—the patient. There is little interaction on a routine basis with physicians utilizing their product. Yet, the service performed by sterile processing personnel in decontamination, packing of instrument sets and sterilizing them safely is vital to positive patient outcome.

The incidences of surgical site infections in the United States are rising. Super bugs, resistant microbes, are challenging our usual infection control procedures. Hospital-acquired diseases are the fourth leading cause of death in the United States. In year 2000, 103,000 patients died from hospital-acquired diseases. Nonetheless, the United States has one of the quickest processing times of any country in the world. Our parameters for sterilization are from three to four minutes in prevacuum steam and 30 minutes for terminal sterilization in gravity displacement steam. Dry time is routinely 20 to 40 minutes depending on load and the packaging material used. In Europe and Japan, processing times are greatly increased over our standard parameters. For example, pre-vacuum steam exposure times are a minimum of five to 18 minutes and exposure time for flash sterilization in Japan is 10 minutes. Where most flash cycles in the United States have virtually no dry time; in Japan a 10-minute dry time for flash is the standard.

Japanese technicians use sterilization cycles with extended exposure time and extended dry time and no absorbent materials in their container systems. German technicians also use extended parameters, but use absorbent towels for wicking moisture. Most countries use prevacuum steam cycles exclusively for steam sterilization, while in the United States, we still use gravity displacement steam for flash sterilizing near the OR. Nonetheless, other countries including Australia and most European countries have virtually eliminated their use of gravity displacement steam sterilization.
There is a universal concern about an established minimum for sterility assurance around the world, yet there is little agreement on sterilization parameters. The French parameters are the longest; the U.S. parameters are the shortest. German standards focus on highly alkaline cleaners for decontamination. In the United States, multienzymatic and pH neutral products are promoted as natural cleaning solutions that are not corrosive to surgical instruments and sterilization containers.

When it comes to instrument processing and sterilization, no universal principles apply. Healthcare professionals need to evaluate the options and weigh the variables. After all, there are no absolutes. Instrument set loads vary, as do packaging materials. Then there is an issue of steam quality and proper maintenance of sterilizers:

- What is the minimum exposure time necessary for sterilization?
- How can we determine when a sterilized instrument tray is dry?
- Which standard should we apply?
- Whom do we trust?

There are also contradictions when it comes to marketing products for decontamination. All sterilization containers, including wrapped organizing trays, need to be fully decontaminated and cleaned prior to sterilization. Many technicians believe their enzymatic cleaners are pH neutral. Some detergents are labeled “aluminum friendly,” but have a high pH value. Alkaline cleaners are particularly corrosive to the anodized aluminum surface of container systems. These same cleaners will eventually corrode the surfaces of surgical instruments as well. Disinfection may cause tray surfaces made of plastic to swell. Enzymatic detergents can weaken plastic for these cleaners that are designed to decompose organic material.

Not all sterilization tray manufacturers have tested their products or applied to the FDA for clearance. Organizing trays for endoscopic procedures may not be validated for kill of spores inside of inoculated lumens, a standard validation study for the sterilization of minimally invasive surgical devices. When it comes to sterilization containers, some manufacturers have fully validated their products and have met the requirement of the FDA for pre-marketing clearance. Remember all
sterilization containers and organizing trays are considered class II medical devices; however, not all organizing trays meet established standards. This is why the FDA and AAMI have organized a working group to provide standards for sterilization containers and organizing trays.

Then, there are instrument sets that are particularly hard to process. For example, sterile processing professionals around the world are particularly concerned about the packaging of orthopedic devices, including implants. These instrument sets are heavy, difficult to transport and carry, and have a large metal mass. They are a challenge to sterilize, and often need to be reprocessed because of torn wrappers and wet loads. In addition, there are issues related to the types of packaging materials utilized and whether these materials are compatible with current sterilization methods. One needs to be concerned about material compatibility and residual analysis, swelling and the absorption rate of certain plastics. Several years ago, most custom organizing trays and case/trays were made primarily of metal. Now, many custom trays are made of autoclavable plastic material or hybrids of metal and plastic.

Like Hans Christian Anderson’s tale the The Emperor’s New Clothes, we are often led to believe what others tell us; we don’t see what is facing us. Despite what end users have reported about wet packs, swelling and cracks in plastic trays, marketing managers from medical companies prefer them. The marketing departments of major medical companies with the best of intentions think healthcare professionals prefer plastic. It is an issue of cosmetics over function. Recently, a major supplier of sterilization containers suggested that plastic is the preferred material for sterilization and disinfection of devices exposed to Mad Cow Disease. This same manufacturer plans to release a new plastic lid for their container system—one with a permanent filter that “never has to be cleaned!”

A number of sealed container systems retain moisture. Some manufacturers claim that, despite wet packs, the
moisture in a container is sterile as is the contents. Most sterile processing and OR personnel know that any moisture in a package means the set must be reprocessed. The only exception is for flash sterilization when the item must be sterilized and then used immediately. Other container suppliers recommend absorbent materials to wick moisture. The FDA continues to review sterilization systems, but some—including sealed containers manufactured before 1976 and organizing trays designed prior to 1989—have been grandfathered and not subject to current guidelines.

Then, there is an issue related to expertise, knowledge of instrument packaging and processing, and the ability to listen and respond to customers’ needs. How many sales persons actually listen? Some of the OEM manufacturers of organizing trays are sheet metal houses specializing in parts for the automobile industry, or they are manufacturers of vacuum-formed trays specializing in products for the cosmetic industry. Material compatibility is essential for current methods of sterilization. Some sterilization trays are being utilized for the wrong purpose.

Do not believe all that you hear. Get the facts. There is information available through the Freedom of Information Act. The FDA has a website that can be accessed by the internet, although some of their information is not current or inclusive of add to file information that may be provided to the agency after submission. Remember to ask your supplier for their validation test results and their 510k. Ask them about the limitations of their device. Confront them if information is sketchy or unbelievable.

Industry executives must possess integrity. Management skills are not enough. The leadership of any organization must support the company’s mission and values, but also be socially responsible and know right from wrong. Unfair competition, based on misinformation, does a disservice to the consumer. It is time for ethical sterilization solutions. This includes factual information, full validation and performance testing, regulatory oversight for all (not just the newest players), and sustainable solutions such as certification, standardized procedures, and guidelines that include an extra measure of safety to assure positive patient outcomes.

It is time for suppliers to adhere to principles of fair play. Compete, yes, but with excellent products, truthful information and sustainable solutions that contribute to patient care.

Marcia Frieze is CEO of Case Medical. She was instrumental in the development of the SteriTite sealed container and the MediTray line of inserts for instrument protection and sterilization. Ms. Frieze holds several patents and is involved on the national level in the United States as a committee member of AAMI, the U.S. standards committee, and as a member of sterile processing organizations. A former social worker, she has worked to develop a full line of products for sterilization and instrument processing with the healthcare community’s needs in mind.

Ms. Frieze has written articles on sealed container effectiveness, infection control issues and sterilization. She has traveled extensively and has visited with healthcare professionals around the world. In addition, she has developed and presented educational seminars for healthcare professionals on the local, national and international level. She holds a master’s degree from Columbia University.