Could you please describe STERIS’s services and products in the realms of infection prevention and decontamination?

STERIS’s mission is to help our customers create a healthier and safer world by providing innovative healthcare and life science product and service solutions around the globe. Specifically regarding infection prevention and decontamination, we provide the broadest range of product and service solutions to the widest global network of healthcare provider, pharmaceutical, and medical device customers. These solutions include washer/disinfectors, steam and gas sterilizers, endoscope reprocessors (high-level disinfection and liquid chemical sterilant), cleaning chemistries, sterility assurance and applied infection control products, onsite and offsite surgical instrument reprocessing, pharmaceutical plant cleaning and decontamination products and services, and postmanufacturing pre-first-use medical device sterilization services.

What do you see as the single biggest advancement in healthcare sterilization during the previous decade?

Our industry has made many great advancements over the past decade. However, it wasn’t too long ago that ethylene oxide (EtO) was widely used to sterilize devices in healthcare institutions. EtO is a known carcinogen and potential source of air pollution. The movement in healthcare institutions to hydrogen peroxide and liquid chemical sterilization to largely replace EtO, along with the great improvements in the handling of EtO in the “industrial sterilization” of manufactured medical devices to change the EtO waste to ethylene glycol (think antifreeze), has been a great improvement to healthcare workers and the environment. In addition, we have seen considerable improvements in washing, disinfecting, and steam sterilization in healthcare facilities, resulting in reduced energy consumption and water utilization and decreased turnaround times. Finally, we have found more environmentally friendly chemistries to use in disinfection and liquid chemical sterilization. Therefore, broadly speaking, sterilization and disinfection have become more user and environmentally friendly.

You played a role in the return of the Kilmer Conference on industrial sterilization. Why is such a conference important? How will it help those companies that focus on infection prevention and decontamination?

STERIS was pleased to participate in the Kilmer Conference, and we appreciate Johnson & Johnson’s willingness to host it once again. Bringing together thought leaders and practitioners of sterilization and disinfection across healthcare provider, pharmaceutical, and medical device spaces to consider the advancements and challenges of
our industry in a learning environment is certainly worthwhile. It has been a privilege to work with a cross section of our industry to help facilitate this endeavor.

**What is a major challenge facing companies that provide sterilization products and services?**

One key challenge is keeping a finger on the pulse of the ever-changing sterilization requirements, which may be affected by the design, manufacturing, and, ultimately, use of the products that are to be sterilized, as well as the products and processes used to do so.

**What is the biggest sterilization challenge that healthcare organizations face?**

As case loads continue to grow, the demand for faster and more reliable turnaround also has increased. How do organizations keep up with the increasingly technology-driven operating room when the space, capital, manpower, and budget to perform a growing number of reprocessing cases per day are limited? Also, as the complexity and diversity of the procedural devices—and the number and complexity of their uses—increases, so does the challenge. This is especially true of more miniaturized and complex electronic devices, such as robotics and endoscopes, used in minimally invasive surgeries.

STERIS works to collaborate with reusable surgical device manufacturers during the design phase to facilitate cleaning and disinfection efficacy.

**During the past couple of years, multiple news stories have surfaced about patients being at risk from contaminated devices. Do such stories simply reflect a greater awareness of the crucial role of sterilization of medical equipment, or do they point to emerging challenges that are changing the sterilization landscape? In other words, is sterilization today more difficult than it was 10 or 20 years ago? If so, how and why?**

We know that we have made great progress in sterilization of medical equipment/devices, particularly in the advanced economies, in the past decades. A century or so ago, the first stage of healing after surgery was infection. We have made orders of magnitude change since those dark ages. However, our burden, recently and going forward, is heightened by the growth of superbugs—those agents that are relatively impervious to various antibiotics. The wide use, and effectiveness, of antibiotics on both a prophylactic and treatment basis has helped form a more powerful set of adversaries.

Naturally, our friends in the pharmaceutical side of healthcare have a role to play, but we must improve our practices and methods to help control the passing of these organisms. Media stories regarding healthcare-acquired infection outbreaks and transmission events are probably a result of this reality, along with greater vigilance and reporting on the part of healthcare institutions, as well as greater news coverage in general. However, the rise of the superbugs, like methicillin-resistant *Staphylococcus aureus* and *Clostridium difficile*, and potential pandemics, such as HIV, H1N1, Ebola, Creutzfeldt-Jakob disease (CJD), and Zika virus, give a lot of fodder for hyperbole in the media, as well as reasonable and unreasonable concern on the part of the public. Infection control, of which sterilization is a part, is not necessarily more challenging (though CJD and other misfolding protein diseases may be a more significant challenge) for the same devices, used on the same procedures, and in the same cycles as before. But our devices are more complex, the bugs are becoming more difficult to kill if they get into the body, and the types of procedures we are able to do are becoming more complex, more miniature, and on more compromised patients. That is the challenge that we must face.

**How have the regulatory requirements for sterilization and packaging changed over the past decade? Would you say they are more stringent or demanding?**

Regulatory requirements are always evolving with the common goal of promoting patient safety. I probably wouldn’t classify the requirements as more “stringent,” but as the requirements evolve, our industry has taken the opportunity to be more specific in our requirements. In addition, and largely overlooked, are regulatory requirements that affect sterilization and disinfection (e.g., energy use, occupational safety, wage and
hour, environmental), as well as those expected from the Food and Drug Administration, Environmental Protection Agency, and/or Joint Commission dealing specifically with infection control. It is the plethora of not-always-consistent requirements among and across the various “additional agencies” that create a lot of complexity for manufacturers and service providers alike. An example that is not infection control specific: The recent regulations affecting electric motor power use and the types of materials used in “plumbing” fittings have affected product development across a wide spectrum of washers and sterilizers. Another example is the impact of California seismic building codes on healthcare institutions as they outfitted central sterile services departments (CSSDs) and operating rooms (ORs). And, that is before we get into cross-nation issues for global providers.

What are your thoughts on the debate within the sterilization community about “how clean is clean” or how sterile a product must be? Do you see a danger in very-high-sterility assurance levels in that they drive up costs without bringing any additional benefit?

Currently, no clear, identifiable standard for “clean” exists. However, the introduction of technology (e.g., protein detection) has provided the market additional assurances and benchmarks to help measure, for lack of a better word, “clean.” But in many cases, if a device isn’t “clean” or with some limit to bioburden, it may hinder sterilization substantially. We’ve clearly established a benchmark of what sterilization means (i.e., a 6-log reduction). We believe that investing in examining current processes to ensure we are meeting current standards, particularly in areas where we have known outbreaks or sources of contamination, is likely to be more fruitful than changing the standards.

Demand for quick turnaround times for sterilization is increasing. How do you address that challenge from clients without sacrificing quality?

The desire for faster turnaround time will never go away. The key is to find ways to allow the CSSD or other processor to be more efficient, while maintaining quality. We can address these challenges via product development, process improvement, and training. In product development, we can help maintain or decrease turnaround time by implementing faster cycles, creating streamlined and ergonomic workflows, providing products that give quicker sterility assurance results, and creating tools that allow for better information (real-time information) sharing between the OR and CSSD. Process improvement, like process mapping and other Lean techniques, can improve flow in the CSSD. Training also is crucial to allow the CSSD to maintain quality yet remain efficient. Continuing education (and certification) for CSSD staff and easier-to-use products and product interfaces all contribute to faster turnaround times.

A common refrain from sterile processing professionals working in hospitals is that instructions for use (IFUs) often can be difficult to follow. Do you believe this is a fair point? If so, how can IFUs be improved?

IFUs are only one part of the solution. During the past several years, there has been an increased effort to ensure CSSD professionals, in conjunction with manufacturers, have a greater understanding of how products should be used. Communication can always be improved. The makers of the devices to be processed/sterilized and the providers of the equipment/supplies to process the devices need to work to make communication on IFUs as clear as possible. At STERIS, we have developed a number of different communication tools in that regard. In addition, the users have a responsibility to train, and reinforce training, on the equipment/devices in question.
How important is it for manufacturers to consider reprocessing requirements throughout the device design process? How does the intricacy or complexity of a device affect its reprocessing?

Closing the gap between medical device producers and reprocessing equipment/consumable manufacturers is vital to the successful design of any new device. Keeping the reprocessing requirements in mind while designing devices is crucial to facilitating a balance between surgeon/user preference and productivity and infection control in CSSDs.

What role do human factors principles—understanding workflow and how professionals interact with devices—play in developing quality products and services?

As is the case in the development of any product that is going to be used by the “general population,” understanding the human factor principles is an important part of the success of the product. Taking into account how the product will be used, how professionals will interact with the product, and how it affects workflow is fundamental to high-quality product development.

How will healthcare sterilization be different 10 years from now?

There are international models of healthcare sterilization that allow industry manufacturers and experts to take on the responsibility of reprocessing devices in large-capacity off- and/or onsite locations—in other words “outsourcing” sterilization—in much the same as is done regularly by medical device manufacturers postmanufacturing. Models such as these may be a significant part of the future of many healthcare facilities, in order to maintain the critical balance between operational efficiency and patient and staff safety. STERIS and Synergy Health have combined to bring these solutions, largely pioneered in the United Kingdom by Synergy Health, to other parts of the world. We also expect to see greater use of information technology and other technologies throughout the decontamination and sterilization process.

I’d like to move away from specific sterilization questions and get your thoughts on leadership. In a time of increased global competition and impressive advances in technology, what do you believe is the single most important leadership quality for anyone working for a healthcare technology company?

I believe in the importance of having an unwavering set of principles and communicating those principles consistently and continuously. At STERIS, dedication to our customers is our number one value, and one of the ways we honor that dedication is by always capitalizing the word “Customer” in our written correspondence. Although we are a for-profit company, we are mission driven, and our mission tagline is to “help our Customers create a healthier and safer world.” We do so by creating value for our associates, who are the only ones who can deliver value to our customers, giving them a safe and rewarding career opportunity. Safety is the number one value for our people, and we are one of the safest industrial companies in the world, and we strive to become safer every day. If we create significant value for our customers and for our people, there should be plenty of opportunity to generate appropriate returns for our shareholders. These three things are what we do: create value for our customers, our people, and our shareholders.

What are you most proud of about your tenure at STERIS?

In short, making demonstrable progress on all three of the areas I discussed in the previous question. In doing so, our people have transformed the company to one that provides a broad range of product and service solutions for our healthcare provider, pharma, and medical device customers on a global basis—from infection prevention, to equipment maintenance, to device repair, to OR infrastructure, to gastrointestinal devices, to CSSD consulting and outsourcing, to hospital and pharma sterilization and disinfection services, and to medical device sterilization.