After a recent string of incidents linking contaminated duodenoscopes to serious bacterial infections and deaths among hospital patients across the country, medical device manufacturers, Central Service (CS)/Sterile Processing Departments (SPDs) and even the regulating bodies that govern them, are under the scope now too. The scrutiny isn't likely to let up any time soon and, according to some, that's exactly what's needed to drive changes that will keep patients safer and healthcare facilities more cost-effective and efficient.

Speaking on behalf of Crosstex/SPSmedical, which makes sterility assurance and other related products, Chuck Hughes, Vice President, Infection Prevention Consulting Services, Cantel Medical, says adverse events are likely to continue unless SPD personnel receive the proper resources and education. "Complex devices, such as flexible endoscopes, ophthalmic instruments, dental hand pieces and orthopedic sets to name a few, require a substantial amount of training and education for staff to comply with very detailed reprocessing steps," said Hughes. "In addition, special equipment and supplies are commonly needed, along with extensive flushing and thorough rinsing with copious amounts of treated water. Not knowing and not having the necessary resources to properly reprocess complex devices is a contributing factor to this problem for sure."
For devices are becoming more complex, many of the SPD departments have

Shawn M. Flynn, Senior Vice President, Customer Operations, Restore Medical Solutions Inc., shares a similar sentiment. "Since many of the devices are becoming more complex, many of the SPD departments have
to take more and more time to reprocess these devices. These devices require the technician to have the critical thinking capabilities coupled with vital attention to detail. The margin for error is becoming increasingly smaller and it’s challenging when some departments are underpaid, overworked and understaffed,” he said. “SPD is one of the most important departments in the entire hospital as they are the first line of defense for disease prevention. As many hospitals consolidate services to include HLD within SPD, it’s absolutely imperative that adequate resources aren’t spared when building, staffing, and operating a sterile processing department.”

Cleaner, safer, more efficient

To assist staff in evaluating how clean instruments are after processing them — and to catch any remaining debris that may have been missed — Healthmark Industries recently released its Flexible Inspection Scope. It’s designed with technology that allows SPD professionals to visually inspect the inside of lumened instruments, take pictures and video record images for effective record keeping. “We also offer the EndoCheck, which checks the cleanliness of the biopsy channel of the flexible endoscope,” explained Matt Smith, Marketing Manager. “Simply swab the biopsy channel of the scope with the included soft-tipped long probe, clip off the swab into the vial, mix the activating agent, shake vigorously, wait and then check for a color change. Depending on the type of test used, a color change indicates that blood residue or protein residue remains in the channel, and should be reprocessed. EndoCheck complies with ASTM Guide D7225. We offer enzyme-based tests, like our 10-minute gram-negative HangTimeKit. It utilizes a unique enzyme detection method, the easy to read fluorometer checks for possible colony formation by reading telltale fluorescence in the recaptured water. If the fluorometer reading is positive for gram-negative bacteria (which includes organisms such as CRE) reprocess the endoscope prior to use. Our innovative cleaning verification products help our customers streamline operations process and stay compliant. By staying compliant, they are also ensuring that their products and equipment are safe to use on their patients.”

Healthmark also makes SPD education available in a way that’s fun and motivating. “We introduced our SP Dollars program to help departments earn points that can be redeemed toward educational materials and programs,” said Ralph Basile, Vice President, Marketing. “Further, our Crazy4Clean.com CEU games provide a fun and free method for gaining valuable education and earning CEU credits from IAHCSMM and CBSPD.”

Having worked in sterile processing for 13 years, Marcus Super, Director of InstruSafe, Sales and Marketing, Summit Medical, says some facilities routinely spend large sums of money on instrument repairs and replacements — costs that could be contained using Summit’s InstruSafe Tray products, which are designed to protect delicate instruments. “At my former job, surgical services spent nearly $300,000 a year on repair and replacement of instruments. Much of this stems from not properly organizing instrument sets with adequate trays,” said Super. “The upfront expense to properly protect and organize instruments can easily be justified by the reduction of instrument repair and replacement within the first year. As you start to add up the expense of needing to repair or replace instruments in these sets it becomes obvious for the need to keep them protected from damage. Through the use of InstruSafe Trays we can start to reduce these problems from day one.”
Innovative Sterilization Technologies’

ONE TRAY sterilization container technology

“This begins with initial use in the operating room and continues all the way through decontamination and sterilization,” Super continued. "Surgical instruments are completely protected throughout the use cycle with medical-grade silicone instrument holders configured in the cover and base of our InstruSafe Trays. The base holders are molded to hold instruments in place while minimizing contact points to improve sterilant penetration of each individual instrument. Sterilization is further improved with aluminum construction for optimal heat transfer and large amounts of perforation that provide superior penetration and drainage. This provides 360 degrees of protection superior to any product on the market.”

Scott Cohen, CEO, Innovative Sterilization Technologies LLC (IST) also provides tray solutions that improve efficiencies. “One of the biggest challenges we hear in the field is the cost and resources it is taking to process OEM loaner and consignment instrumentation and implants. Some of the knee and hip revisions we have seen involve over 30 pans for one surgery, one had over 52 different pans needing processing. There is a tremendous cost to the hospitals to process these and in the world of DRG (diagnosis-related groups) payments these costs hit directly on the bottom line,” said Cohen. “Our ONE TRAY sterilization container technology becomes so important in reducing preparation and processing terminal sterilization times by 75 percent compared to the existing technologies. With ONE TRAY’s preparation/processing speed and efficiency we offer facilities cost savings of over 40-plus percent versus blue wrap and no torn wraps or wet paks to worry about. Our savings come from much less needed personnel, less energy and water used, and 95 percent less waste.”

Sterilization Container technology has not changed in over 40 years; value or savings needs to be obvious, traceable, and significant for wide acceptance from supply chain," Cohen continued. "Implementing a small amount of ONE TRAY containers can completely change the way an SPD manages instrumentation and situations. ONE TRAY allows for all of the unforeseen changes that occur to be reacted to in a very quick time frame. Prior to ONE TRAY there was a three-plus hour terminal processing time needed or IUSS (immediate-use steam sterilization) was involved in reacting to these situations. This efficiency, at its simplest concept, will reduce if not eliminate the SPD's/OR's need for redundant instrument/set/power purchases.”

Flynn (Restore) describes a typical SPD challenge and how his company has also come up with a unique solution. "If you have ever worked in an operating room or sterile processing, you are already familiar with the jumbled basket of dirty surgical instruments that find their way from the OR to SPD for decontamination, prep and pack, and sterilization following every surgical procedure," he said. "Any SPD employee can tell you the challenges of reprocessing and sterilizing thousands of surgical instruments. When instruments, such as rigid scopes, light sources, and flexible scopes, are piled into a basket and baskets are in turn stacked upon each other, immediate deterioration of quality and functionality occur. Since instruments have to be manually cleaned individually and then mechanically cleaned as a set, it can literally take 15 to 20 minutes to manually decontaminate a set of instruments using proper procedures. On occasion, residual bio-burden can find its way on the prep and pack side, which triggers re-work. The frequency of this re-work is a manifestation of inefficient processes. When people feel rushed for quicker OR turnovers and SPD is being called to expedite reprocessing of certain sets, sharps can find their way to SPD thereby becoming a workplace injury. Depending on how long that case cart sat idle, it may be impossible to determine which set was used on which patient. This is an unnecessary risk that no employee should endure.”

Flynn says restringing and spraying the instruments with enzymatic solution at the point of use in the OR can help solve those problems. "This solitary action
makes it easier to recount instruments on the back table and accurately account for them. It also enables a quicker and safer inspection in SPD, which in turn delivers cleaner instruments to the OR in a more efficient manner," he explained. Flynn also noted that although the FDA and the Association for the Advancement of Medical Instrumentation (AAMI) recommend that instruments be placed inside the washer in an upright position, doing so was difficult. "Prior to Restore there was not a product on the market that facilitated an organizational element in-situ the containment device," said Flynn about the company’s Intelligent Modular Sterilization Tray System. In early March, Restore also launched its Restore iQ as an extension of the tray system, which was designed to be used in conjunction with a hospital’s current surgical baskets, enabling safer and faster reassembly and organization of ringed-handled instruments for more effective point-of-use cleaning and decontamination and increased productivity. "With the instruments in an open and upright fashion, it is easier for the SPD tech to inspect and reassemble instruments, thereby lessening the touch points within the surgical sterilization continuum," Flynn said. "Fewer touch points translate into fewer sharps-related accidents for staff, reduced capital budget for repairs and replacements, decreased assembly time, and increased focus on inspection and functionality. The bottom line is consistent cleaning with fewer touch points translates into fewer delays associated with missing or contaminated instrumentation and better quality healthcare for patients."

Gusanders (Pure Processing) says it's not uncommon for SPD to be misinformed about the importance of pre-cleaning, which can be overlooked when sonic irrigators are used. "Many SPDs don’t understand sonic irrigators do not allow you to skip pre-cleaning," he said. "These pre-cleaning steps are still required by equipment manufacturers as well as instrument manufacturers. The FlexiPump Independent Flushing System is a cost-effective automated alternative that helps assure compliant, high quality flushing, provides much greater workflow capacity, and supports worker and patient safety. The FlexiPump is used on all types of reusable lumened devices, including rigid and flexible scopes, robotic instruments, minimally invasive surgical devices, ocular devices and suction tips, which must be flushed thoroughly and consistently to assure complete removal of debris and soils during pre-cleaning."

Protecting the health and well-being of SPD workers is also critically important, says Gusanders, noting that traditional manual flushing processes with syringes can lead to repetitive motion injuries. "Imagine a tech standing at the sink manually flushing a single endoscope channel over and over again with her 60 ml syringe. Now, imagine a department with three FlexiPump systems at that same sink (two on the wall and one on the counter), each pump with three tubes connected to a device, automatically flushing nine lumens at the same time, each in 60 seconds! It’s not hard to see that having these compact, cost-effective systems at your sink can save time and greatly reduce manual labor, which can free up your technicians for other duties in the workflow. National and international regulating bodies have been calling for more robust reprocessing quality systems in the wake of infection outbreaks around the world. They have flagged the need for standardized, consistent and repeatable processes, which can be enhanced by using automated systems where appropriate. The FlexiPump system injects consistent, repeatable flushing into the pre-cleaning process, with simple, intuitive operation that is easy to train and a system that’s easy to maintain."

Dependable chemistries and sterilizers

For dependable and effective
disinfectant chemistries, speaking on behalf of the Henry Schein SPD product line, Matt Beauchaine, Channel Manager, Crosstex/SPSmedical, says Henry Schein brands have gained a reputation of improving existing products with proprietary technologies — and MaxiCide OPA28 is a perfect example. "OPA chemistries have been on the market for some time now; MaxiCide OPA28 improves on this technology by offering a longer reuse period and faster disinfection time through its proprietary formula," explained Beauchaine. "MaxiCide OPA28 is an ortho-phthalaldehyde-based high-level disinfectant that lasts longer and works faster than competing chemistries. MaxiCide OPA28 has a reuse period of 28 days (two times longer than 14-day chemistries) saving facilities significant dollars. The product also has a reduced 10 minute manual soak time, compared to 12 minutes with competing OPA products. The result is an additional reprocessing cycle every hour! Maxima Sterilization pouches are another good example. These pouches use Sure-Check technology, a patent pending technology, where every pouch includes a multi-variable internal chemical indicator. Additional internal indicators are not needed, thus saving departments time, money and reducing the chance for errors. For facilities using Class 5 integrating indicators, the internal indicator serves as a back-up should staff forget to include an integrator in a pouch."

Jim Wetzel, Vice President, Sales and Marketing, TSO3, says the STERIZONE VP4 sterilization technology is the only dual sterilant, low-temperature sterilization product on the market that processes heavy, mixed loads in one cycle with vaporized hydrogen peroxide and ozone. "Because our STERIZONE VP4 sterilization technology is able to process a mixed load of up to 75 pounds containing flexible scopes, rigid scopes, cameras, cables, etc., this efficiency allows us a 3:1 ratio in processing capability per load over competitive equipment," Wetzel asserted. "This translates to an immediate cost savings of a near equal ratio while increasing efficiency and equipment inventory turns. Also, because of our single cycle capability, it removes the potential for operator error in cycle selection. As the complexity of surgical technology increases more and more, items are being brought into the OR that require sterilization or reprocessing, including more scopes. Often times these items include electronics or are lensed and unable to withstand classic steam sterilization. This increases the need for more device friendly, low temperature process. Couple this with a desired more rapid turnaround time and environmental concerns and it drives the need for more productive and efficient processes such as oxidizing processes."

According to Joney de Souza, Group Product Director, Infection Prevention, ASP, the STERRAD 100NX System delivers innovative hydrogen gas plasma technology that is safe for patients, instruments, health care workers and the environment.

"The STERRAD 100NX System provides unsurpassed productivity with extensive IFU endorsements from the medical device manufacturers for low-temperature sterilization, easy-to-use features and functionality and shorter cycle times to increase throughput and efficiency," said de Souza. "Compared to steam sterilization, STERRAD technology reduces instrument damage that can save a typical hospital one-third of its
annual repair costs or approximately $18 for each scope processed. Our proprietary technologies and services such as our hydrogen peroxide monitor that measures sterilant concentration during cycle and gas plasma technology appeal to SPD customers as they are unique to ASP." ASP also developed the STERRAD Sterility Guide (SSG), available online and as a mobile app, to help users comply with IFUs in real time and quickly and easily identify which devices fall within STERRAD System sterility claims. "Another key feature is the system's ability to adapt to new technology, such as STERRAD 100NX System expandability and STERRAD Sterility Guide validations," said de Souza. "This increases the value of the investment for a facility."

Sterilization product manufacturer Tuttnauer USA recently launched a new healthcare sterilizer model that easily fits into very small spaces, making it an ideal choice for operating rooms and small- to mid-sized outpatient clinics. Jake Miller, Sales and Marketing Manager, says the new 5075HSG model has a 19.5-inch diameter and 29.5-inch deep chamber with a built-in steam generator, pre/post vacuum cycle capability, and vacuum pump for efficient air removal and low water usage. Furthermore, Miller says Tuttnauer sterilizers' non-proprietary components make their machines easier to maintain since replacement parts can be obtained more readily through the years — an advantage that "lowers the total cost of ownership compared to other manufacturers," he said.

**Tracking and accountability**

As more facilities make instrument identification and traceability a priority, new products and services are available to help in that effort too.

Censitrac, Censis' customizable instrument tracking system is one example. David Craig, Director of Clinical Initiatives, says Censitrac's main features include tray and instrument level tracking, patient care equipment tracking, full-scale electronic sterilization documentation, case cart tracking, effective tracking for flexible endoscopes, and special traceability options for vendor loaner sets.

"Censitrac generates a unique load number for every sterilization cycle for which it is used and is forever associated with the specific items in the sterilizer load," said Craig. "The load numbers contain specific information about the items, the parameters of the sterilization cycle, the biological indicator (BI) and chemical indicator (CI) results of the processed cycle. The BI interface "monitors" the correct format for lot numbers, avoiding data entry errors. The interface prevents a BI's results (positive or negative) from being saved if the determined incubation period is not fully met. An efficiency aspect includes tying the results of the BI to the Censitrac generated sterilizer load number.

"Censitrac also offers personal
accountability in all aspects of its functions,” continued Craig. “Who assembled a set, how long did it take, who was responsible for sterilizing the load, who checked the cycle for correct sterilization parameters, who picked a case cart, where was the instrument set’s last location scan and who put it there? Management has full capability to see whatever detail he/she wants to see for accurate and efficient location of items. Censitrac offers ‘alerts’ or ‘warnings’ and documents the technician’s response to the warning.”

The system also has a preventative maintenance feature that Craig says can provide a measurable ROI by stopping unnecessary instrument repairs before they occur. “Prevention of a costly and delicate flexible endoscope being inadvertently placed into a steam sterilizer can result in costly repair or replacement,” he said, adding that Censitrac even assists in improving work flow and staff scheduling. “The extensive reports that are available allow the manager to trend work load and work flow, justify the need for more staff, reallocating hours worked for the staff — putting them where the volume of work is, versus a traditional shift.”